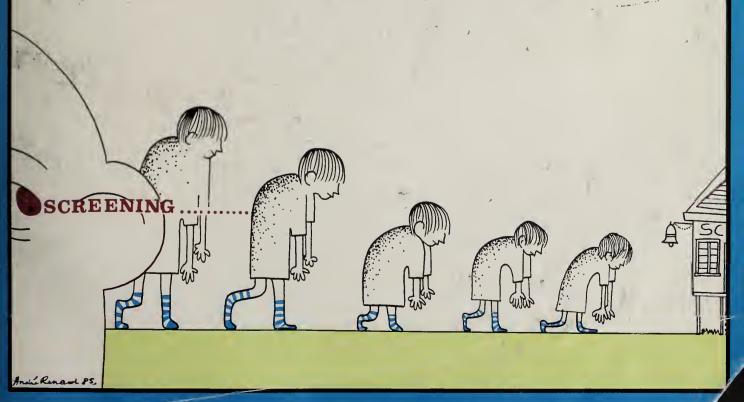


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October 1985

NON 4 1985 Doctors Helping Doctors''

Vol. 2 - No. 4

AMA IP Conference In Chicago in April

The American Medical Association has announced that its Seventh National Conference on the Impaired Physician will be held in Chicago, April 10-13, 1986.

The Conference, conducted every other year, will have as its theme, "Reaching Out to Physicians . . . Their Families . . . and Allied Professions."

The 1986 conference will provide a forum for exchange of ideas and innovative approaches for those who work with impaired professionals, provide information to help implement and strengthen current programs, and stimulate the development of cooperative ventures among the profes-

Half-day sessions sponsored by national health organizations plus the AMA Auxiliary and the AMA Departments of Medical Student Services and Resident Physician Services will be featured. These will include presentations on impairment programs existing within these groups as well as examples of cooperative programs among various professions and organizations.

Additional information about the conference may be obtained by writing to: Ms. Janice J. Robertson, Department of Mental Health, AMA, 535 North Dearborn Street, Chicago, Illinois 60610.

Dr. Rogers to Chair Section on Dependency

For the sixth consecutive year, the Committee on Impaired Physicians will sponsor a scientific Section on Chemical Dependency during the 1986 Annual Meeting of the Florida Medical Associa-

The Annual Meeting will be at the Diplomat Hotel in Hollywood, September 17-21, but no specific date has been set for the chemical dependency program. Arvey I. Rogers, M.D., of Miami,

(Continued on Next Page)

Impaired Physicians Generate Costlier Malpractice Settlements

A preliminary study indicates there is a definite connection between physician impairment and medical malpractice, a New Jersey expert in chemical addiction told a Florida Medical Foundation-sponsored workshop last month.

David I. Canavan, M.D., Medical Director of the Medical Society of New Jersey's Impaired Physicians Program, said his survey was based on the cases of 61 impaired physicians in his program. While the number of malpractice cases generated by this group appeared to be smaller when compared with non-impaired physicians, the cost of settlement of each case was significantly higher, Dr. Canavan said.

Drinking Habits of Elderly Are Studied

The conventional image of people turning to alcohol when faced with traumatic events does not generally hold true for the elderly, research being conducted at the University of Florida in-

UF Sociologist Ronald Akers expected to find that the more shattering experiences an elderly person suffers, the more he or she would drink. "We found just the opposite effect," said Akers, who is surveying the drinking habits of 1,400 persons over the age of 60 under the sponsorship of the university's Center for Alcohol Research.

The elderly experience a high share of "significant life events" which include death of a loved one, being fired, retirement and divorce.

"If drinking is a response to these life events, you would expect to see an increased rate of drinking or problems associated with drinking developing late in life," Akers said. "But we found a negative correlation between life events and drinking. In other words, the elderly people reported they drank less than the elderly who had not been faced with the

"It could be that older people are better able to cope with stressful situations and are better able to plug into a supportive social network," he continued. "Perhaps the idea is that they have seen it all before and know 'This, too, shall pass."

"We are going to investigate this further," Dr. Canavan told participants in the Committee on Impaired Physicians' Sixth Workshop on Intervention with Impaired Physicians on September 28. "We hope to get a larger sample by cooperating with other states."

Dr. Canavan's program, now in its fourth year, has a current annual operating budget of \$237,000, most of which is provided by two medical malpractice insurance companies in New Jersey. The state medical society and state veterinary and osteopathic organizations contribute the remainder. He quoted one malpractice insurance official that if the program spares his company one settlement a year the contribution is more than repaid.



Dr. Canavan

Dr. Canavan, who became the nation's first full time medical director of a state societysponsored impairment program when he took the New Jersey post 3½ years ago, was the principal

speaker at the workshop, which attracted about 50 physicians, nurses, veterinarians, podiatrists, pharmacists, attorneys and others. It was the first workshop program arranged by Roger A. Goetz, M.D., Medical Director of the Florida Impaired Physicians Program, since he came to Florida in February.

(Continued on Next Page)

Another speaker, John C. Eustace, M.D., Clinical Director of the Addiction Treatment Unit at Mt. Sinai Hospital, Miami Beach, told the audience that "most of the signs and symptoms of addiction are still behavioral."

Eight per cent of his patients have a second neuropsychiatric disease, and "we are going to see more of this because of all this use of drugs," he said.

He appealed to physicians planning to intervene with impaired colleagues to do their homework because the two principal causes of failure of intervention are inadequate preparation, including failure to get facts verified, and inappropriate timing.

"If we don't do something for ourselves and our colleagues, no one else is going to do it," he admonished.

Dr. Eustace's partner, Jules Trop, M.D., recalled that before Alcoholics Anonymous came on the scene a half century ago, alcoholics "went to jail, died or went crazy."

Now, with modern treatment methods, the recovery rate is high, he said.

He agreed with Dr. Eustace that a significant number of patients entering treatment exhibit one other primary disease and this means that "addictionology and psychiatry are going to have to work more closely together.

"This disease of addiction is chronic and it is incurable. We don't have pills, radiation and surgery. What is the percentage of recovery? You can do anything you want with statistics. But given proper tretment methods and a willingness to work at it, the potential for recovery is 100%, and there is no other incurable disease this can be said about."

Treatment, he said, must address all the physical, mental, psychological, familial and spiritual aspects of the disease, and "physical is the easy part."

The aim of treatment, he continued, is recovery and "total abstinance from all mood altering drugs." Many patients undergoing effective treatment "start to feel better than they ever felt before they got the disease."

Dr. Trop acknowledged there is sometimes recidivism among addicts, but "for some of us relapse is necessary for recovery."

"A good program has to use Alcoholics Anonymous or Narcotics Anonymous

mous for a continuing support system," he said. "The disease doe not go away. The monkey on your back is not dead. He is sleeping."

Ronald J. Catanzaro, M.D., and his associates from the Palm Beach Institute in West Palm Beach, stressed the need to treat not just the addict but the family as well. PBI Program Director Jerry Singleton, M.A., said the symptoms of codependency include preoccupation with the disease of the alcoholic, a need to control and manage, emotional withdrawal and a sense of gloom and depression

Lynn Hankes, M.D., Director of the Addiction Treatment Unit at South Miami Hospital, discussed the disease concept of chemical dependency.

"Somehow it's not a normal disease," Dr. Hankes told the audience. "It's the only disease that tells the patient he is not sick. But until the patient accepts the fact that he suffers from addictive disease, recovery is not possible."

Wilson Jerry Foster, J.D., a Tallahassee attorney who represents licensed health care professionals in disciplinary proceedings before their licensing boards, reviewed those provisions of the Medical Practice Act which relate to impairment. He also discussed the legal responsibilities of physicians to report impaired colleagues.

Dr. Canavan said he works with a three-tiered impaired physicians committee in New Jersey. The Executive Subcommittee, consisting of 13 members including students, residents and auxiliary members, works with the salaried staff in implementing policy and developing procedures and coordinates impaired physician activities in various regions of the State.

The next level is the Panel of Monitors and Intervenors which documents information, intervenes and participates in after-care monitoring. The third is the Human Resources panel consisting of physicians, spouses and others who can assist in various ways with the program and individual cases but who are not required to attend the committee meetings.

Dr. Canavan said he is not aware of any case in which an impaired physician sued a committee because of an intervention.

"Blowing the whistle on an impaired colleague is an act of love," he said. "We need to intervene early while there is something there to save."

Veterinary Executive Gets Committee Post

H. Larry Gore, D.V.M., of Orlando, Executive Vice President of the Florida Veterinary Medical Association, has been appointed an Advisory Member of FMF Committee on Impaired Physicians.



Dr. Gore

Dr. Gore and his organizations have been longtime ardent supporters of the Impaired Physicians Program. Several impaired veterinarians have been admitted to treatment through the IPP, and the

FVMA earlier this summer contributed \$6,000 to the program.

"I am honored and extremely appreciative that you and the Florida Medical Association Board of Governors have approved my appointment," Dr. Gore wrote to FMA President Luis M. Perez, M.D.

"Dr. Gore has been a true friend of the FMA and particularly our impaired professionals program," Chairman Guy T. Selander, M.D., of the Committee on Impaired Physicians, commented. "The program stands to benefit greatly through his official involvement."

Dr. Rogers (Con't)

has been designated program chairman, and the Florida Chapter of the American Medical Society on Alcoholism will be invited once again to co-sponsor the program.

The annual Section on Chemical Dependency is the focal point of the Committee's efforts to keep the medical profession in Florida up-to-date on scientific and other developments in the chemical addiction area.

He cautioned, however, that it is wiser to postpone an intervention until the essential facts on which the case is based are verified.

The intervention workshop was part of the Committee's continuing efforts to keep the medical profession in Florida up to date ondevelopments in all areas of addiction including intervention. The Committee has not determined when and where the next workshop will be presented.

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COVER

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Indigent care—a problem for all citizens

In the sixties, when I started practicing medicine in Florida, it was taken for granted by all the physicians that a certain number of indigent patients were going to be seen every month in the office or accepted for admission to the hospital through the emergency room. It was considered part of the contribution to society by the physician and an integrant part of the profession.



Along came Medicare and Medicaid and the attitude of the physicians and the hospitals began to change. Everyone expected to be paid something by someone or by a third party, and the commercialization of medical care became intensified.

A few years later the liability crisis developed, compounding the problem. Certain groups of lawyers who found the "Horn of Plenty" in suing doctors and certain patients who in their greed look at this as a means of instant wealth have complicated this situation.

The fact remains that the medically indigent still exist; a significant percentage of the state's population can qualify as such. These people are very much in need of medical care. We have to devise a system which will provide medical care without compromising quality.

These patients, as a rule, present the most difficult problems, mainly because their lifestyle is so borderline from the standpoint of hygiene, self-care and nutrition. This easily complicates the cases and makes them more difficult to handle.

The problem is a problem of society. It has to be approached through public health and the citizens of the state. The concept of using a hospital tax to raise the necessary funds to care for the indigent is, in our view, a highly unfair solution. It is an added burden to patients treated in a hospital setting, while the rest of the population contributes nothing to the solution.

A more equitable arrangement would be an increase in the sales tax, where a moderate amount will go a long way, and all citizens will pay their fair share for the common good.

These tax dollars would have to be earmarked specifically for the purpose of financing the care of the medically indigent only. They should not be used to fund other types of welfare programs.

The Florida Medical Association is willing to pursue the study of all possible solutions. We are willing to meet with legislators and the Department of HRS representatives until a workable and realistic plan is developed to ameliorate the growing problem of the medically indigent.

Our efforts must be geared toward keeping our commitment to equal access to good quality care to all people regardless of economic means and status in society.

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New rules, new dilemmas

Editor's Note: This editorial appeared originally, under a different title, in *The Stethoscope* of Volusia County Medical Society, Winter issue, 1984. It was expanded and modified by the author for *The Journal*.

The practice of medicine used to be a simple transaction: the physician examined the patient, rendered a service, and got paid for it. The patient usually did not question the physician on what he did; neither did anybody else. But as medical practice has become more complex and expensive, usually involving the employment of an array of diagnostic and therapeutic services and procedures, and as increasing competition in medicine is compelling a number of physicians to devise certain economic strategies, new concerns and new questions have popped up. One major focus by patients and recently by the government, insurance companies, and the medical profession is on the physician: what he does, how much he does, and whether what he does is appropriate or not. The reason for this changing and often skeptical attitude is the fact that the modern physician has the potential to expand his practice and offer a variety of services in which he may have a vested interest. More services means more money, and therein lies the crux of a thorny dilemma: the conflicts of interests that are rampant in today's medical setting.

In times past, physicians did not have to confront such conflicts of interests. Ethical restraints and government regulations made it impossible for physicians to make profits except for fees generated from direct services to patients. A classic and oftenquoted example of the old rules was the prohibition on owning drug stores by physicians. This made a lot of sense. Physicians, in writing prescriptions, did not get sidetracked by the possibility of extra profits

while seeing their patients. This aura of incorruptibility conferred by such rules kept the public image of physicians clean and unsullied. The public, after all, does not expect physicians to be businessmen at the same time.

But we are in a new age of medicine and the rules of the game are changing fast. With new government regulations that are altering the patterns of medical practice and promoting more free enterprise in the medical marketplace, an increasing number of physicians are scrambling to partake of opportunities not previously available. Despite the traditional ethical restraints, more physicians are now practicing like businessmen. It is not without reason that "entrepreneurship" has become a favorite buzz-word in many medical circles today. The more procedures and services he employs in his office, and the more financial interests he has in all sorts of ventures — whether these be with hospitals, corporations, insurance companies, or other physicians — the more the physician stands to gain from his practice. This practice is abetted by the fact that Medicare and medical insurance companies dole out hefty reimbursements for almost everything. Under this new and unfettered climate, it is not unusual for many physicians to see their incomes doubling or even tripling without working additional hours.

It is only fair to state that the majority of physicians who have equipped their practices with additional services and paraphernalia did so for the convenience of their patients. A case in point is the setting up of small laboratories by primary care practitioners in their offices. Drawing blood samples, doing simple tests, and sending specimens to commercial laboratories for more complex tests is not only more convenient for patients; it is also much less expensive than sending patients to hospital

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laboratories, for example. New and more stringent Medicare reimbursement policies for outpatient laboratory work also obviate the possibility of abuses. Nevertheless, despite the honesty of most physicians, their increasing involvement in profitmaking medical ventures disturbs the equanimity of those who feel that the situation deserves further scrutiny.

There is nothing inherently wrong in making a profit out of one's honest work; but at the same time, it can also impel certain unscrupulous physicians to do things in blatant disregard of patient's interests. The allegations, for example, that some physicians have been consorting with certain manufacturers of pacemakers and intraocular lenses for financial favors, if true, can only fuel suspicion that physicians cannot be trusted. What they do may be legal and medically justifiable on the surface, but is it right and ethical? Part of the problem is the fact that medical practice is getting grossly commercialized, with the rules of the marketplace having replaced largely the older ethical codes. Another problem is the lack of effective mechanisms within the medical profession to monitor physicians' activities. Most physicians who abuse the system get caught usually by accident by other physicians or by a few vigilant patients who know when some hankypanky is going on.

It may be argued that most current arrangements which allow physicians to participate in economic ventures are above-board and perfectly legal when tested against the profession's most stringent standards. For example, physicians banding together to open a diagnostic laboratory or an imaging center are at most just displacing other third parties like pathologists, radiologists, or a big corporation from reaping the usual profits, or perhaps sharing the profits with them. A group of surgeons opening an ambulatory surgical clinic may in fact be saving their patients a lot of money, even if this means greater economic returns for the surgeons in the long run. For those who feel that there are still conflicts of interests in such situations, public disclosures by physicians of their interests in these enterprises, as is now required by some states, may quell the anxieties of skeptical physicians and the public. Patients at least will know from the outset that something is not being withheld from them. Whether such public disclosures will curb potential abuses of the system can be answered only with time.

Amidst all the developments swirling about them, physicians, like Caesar's wife, must be above suspicion and ultimately must abide by ethical codes of conduct rooted deeply in the medical profession. The changing mores in medical practice must not distort our perspective that, as physicians, we are the trusted guardians of our patients' interests. If we do not wish to live by the old-fashioned

values which have distinguished our profession in the past, the government and other outside forces surely will step in and start dictating to us, as they have already done. It is a simple choice of eschewing our principles or adhering to the creed of doing what is right.

R. G. Lacsamana, M.D. Editor

The only alternative

"Working men of all countries, unite!" For more than a century this final sentence of *The Communist Manifesto* co-authored by Karl Marx and Friedrich Engels has echoed throughout the world. It is most appropriate now for a similar phrase — Physicians of all counties, unite!

The American physicians are on a watershed between a dying medical system based on individualism and a collective medical system being formed in which the supposed free development of each will be the condition for the free development of all.

It is fashionable for many physicians to talk, almost complacently, of the rendezvous with doom in socialized medicine. Some physicians feel that they have already been robbed of their will power and individualities and are flies in the web of an irascible spider called bureaucracy. Physicians must feel like little atoms trying to maintain their own sanities and equilibriums in the midst of all increasing molecular upheaval.

The medical bureaucrats are pregnant with possibilities that the prophecies of the doom of organized medicine in America will soon be realized. The prophecies of doom are heard today with increasing frequency; some of our national leaders claim that the physician's personal and social future is guaranteed by our material effectiveness. These realists are ignorant of the hard facts. They do not see the emptiness and planlessness of the average physician's life. They do not believe that the average medical doctor lacks faith in the national medical associations. They do not see that if this lack of faith continues, it will incapacitate organized medicine.

Some physicians question the value of the methods of associations into which the strands of organized medicine are woven. Some wish to strengthen and extend the ties while others wish to reexamine, reduce and even eliminate the enmeshment of medical associations and specialist societies. Nonparticipation by physicians weakens the web of interdependence.

Physicians must abandon the quietistic attitudes towards nationalized/socialized health care. The present state of affairs can never be remedied by

editorials alone or bogus gestures of resistance. Physicians must not remain insulated from reality the often cursed AMA with its official answers and actions cannot solve all the problems. The silent majority can no longer justify their inactivity.

Isn't this the time for the silent and inactive physicians to strip off exterior trappings and to realize their own central ego-consciousness and

spiritual nature more perfectly?

Physicians cannot be isolationists from the organizations that represent them. We practice in a complex professional, economic and social framework that responds to a variety of pressures. Alone we are unable to exert much influence on that framework. Collective strength depends on the individual physician/county/state/national organization symbiosis.

There is a tendency for most physicians to believe somebody else will solve the problems. Somebody else will mend the leaks of the liability insurance dikes. Somebody else will remove the inequalities in fee schedules, beautify the dehumanized medical landscape, vindicate the innocent and punish the wrongdoers. Most physicians will not overcome the habit of "letting George do it."

These are not the times for a medical discipline of silence, simplicity, contemplation and selfeffacement. This is not the time for a medical mysticism of introversion and withdrawal. The silent medical majority can no longer justify their inactivity.

An active medical majority can regain the power and dignity of the profession and can vehemently thrust forward as an entity charged with energy and structural in specific ways that will have no expressions of weakness and self-negation.

Inactive physicians can and must overcome the inertia of channeled routine. Physicians affiliated for action and possessing some measure of resiliency, drive and endurance can stimulate the powers that be to make changes.

With conciliation, adaptation and dialogue, the active medical minority can attain unity and solidarity with the silent inactive medical majority. Together, the medical profession could be an inexhaustible source of creative dynamism.

How much longer will physicians be indifferent and helpless to the bombardment of their battered egos with books, speeches and articles dramatizing their superfluities?

How far will the diversifying factors of the medical bureaucracies' pendulum go before the silent majority and the active minority of medicine unite?

All physicians should remember the words of William Jennings Bryan, "The humblest citizen of

all the land when clad in the armour of a righteous cause is stronger than all the hosts of error.'

Physicians of all counties, unite! This is the only alternative. United, we can see medical bureaucratic caprice curtailed!

> Edward Pedrero Jr., M.D., Ph.D. Contributing Editor Tampa

Battling the ghosts of vesteryears

Practicing medicine today is not an easy task. In fact, it is downright frustrating as we must not only keep abreast with new medical technology, but must also face decreased public confidence and occasional animosity from a large segment of the patient population. In thinking about how we as physicians happened to end up in this undesirable position, it has become clear to me that, while we must accept our share of the blame for this turn of events, it is also apparent that there are other factors involved, most of which we did not manufacture or cause to occur. Ironically, we are, to some degree, a victim of ghosts past and at the same time answerable to the new technological society in which we presently live. By this, I mean that we may not be able to shed our comparison with the image of the "old-time doctor" and its implied attributes of goodness, noble purpose, and a caring person. This is in contrast to the modern caricature of doctors with our implied image being one of uncaring and money-grabbing individuals, unavailable to patients, and a danger to the public at times. At the same time, modern day physicians are held accountable to standards which approach almost perfection. We are expected to practice and be familiar with all the latest technology. If we falter in our knowledge or application of this technology, the patients may extract their pound of flesh in the form of a multimilliondollar malpractice suit.

As I pondered these thoughts over and realized how we came to this end, I have come to several conclusions. The first is that being compared with the image of the old time doctor, which by its mere mention conjures up almost a priestly vision, we will never measure up. The simple fact is that no profession can stand up to this ghost of the past. The public has an image of what the doctor of yesteryear was: he was loving, caring, unselfish, unmindful of his own welfare, unconcerned about money, and all knowing. This is the scale by which we are measured by a large share of the public. Not only is it a comparison that is critical of present day doctors; it is also erroneous. Alas, not only are we compared to an

idealistic example, but one which probably never existed and was in fact disliked and distrusted by a large portion of the public of his time. Physicians from 1900 to 1950, which is usually the period in which the "good doctors" lived, as perceived by the public today, were not as many have painted them to be. Medicine was not hailed as a great healing art in that period of time. This was a result of several things. Scientific medical education had just been implemented in the years after the Flexner Report of 1910 and many graduates of inferior medical schools or apprentice programs were still practicing in great numbers. Medical quackery with worthless medicines and gadgetry abounded in the 1920's and 30's. Medical specialization boards did not really get off the ground until the 1920's, with the result being that much specialized surgery was being done with terrible results. The government had only recently passed any laws designed to protect the health of Americans. The public knew this and tended to shy away from doctors if at all possible. If major surgery or illness was involved, those who could afford it went to the few prestigious medical centers of America. Those who could not had to endure the ministries of the local profession, but most feared and loathed it.

It was almost impossible to separate quackery from accepted medical doctrine, which may have done more harm than the quackery. How then did the present-day perception of the "old-time doc" emerge? The old-time doctor is what they would like to have. However, when they had it, they really wanted something else. They wanted a doctor to cure them. They wanted the Mayo Clinics, the John Hopkins Hospitals and all the other wonderful innovations which the emerging age of technology promised them. No, the adoration and nostalgia was not for the medical care. It was because physicians are remembered and revered not as physicians, but as members of a priestly class. Since the healing aspect of medicine was very limited, the role of physicians became one of comforters of the sick and friends of the bereaved. I suspect that the number of physicians who were actually this caring were no more on the average than can be found in our present day physician population. However, no matter how small the percentage of physicians of yesteryear, who fit this mold, the present day perception has assigned it a composite picture and we are consigned to being compared to a ghost.

Ironically, the very thing which the public wanted prior to World War II — medical care based on scientific principles — has now come about, yet the very advance of technology has led to more troubles. This scientific revolution has led to new means of treatment with antibiotics, organ transplants, etc. We as physicians have immersed ourselves with years of residency and specialty training, but the price of medical care, as you would expect, has gone up. We find ourselves in the position of delivering more modern technological care than our forefathers and doing it at the request of the public. Yet, the more medical care we deliver, the more we are compared unfavorably with our medical ancestors. It is a paradoxical situation.

This is not to justify unfeeling physicians nor to say that compassion and technological competency are mutually exclusive. Indeed, I feel, as most doctors do, that we as physicians have to be more caring, more compassionate and more responsive to the needs of the public. Somewhere along the line after World War II, these qualities were subjugated as we delved more into the miracles of modern medicine. We are now at the point where we are able to give the best medical care in the world, but apparently are less liked than our medical ancestors who gave very little medical care. The physicians of the past probably were more caring and spent more time with their patients than we today do. That is partly because they had little else to offer. At the same time, I recognize that there is some validity, indeed much validity, in the complaints against the physician today in which we are painted as less than caring individuals. Again I feel that technology and caring can be mutual and complementary attributes of current medical practice. But in being compared with the ghosts of the past, we will never "pass muster".

What we need to do is to strive to incorporate in our new technological approach those aspects of yesterday's medicine which we all recognize as good and desirable traits.

> H. Frank Farmer, M.D., Ph.D. Historical Editor New Smyrna Beach

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Brief Summary of Prescribing Information.

Indications and Usage: Management of anxiety disorders or short-term relief of symptoms of anxiety or anxiety associated with depressive symptoms. Anxiety or tension associated with stress of everyday life usually does

Effectiveness in long-term use, i.e., more than 4 months, has not been assessed by systematic clinical studies. Reassess periodically

Contraindications: Known sensitivity to benzodiazepines or acute narrow-angle

Warnings: Not recommended in primary depressive disorders or psychoses. As with all CNS-acting drugs, warn patients not to operate machinery or motor vehicles, and of diminished tolerance for alcohol and other CNS depressants.

Physical and Psychological Dependence: Withdrawal symptoms like those noted with barbiturates and alcohol have occurred following abrupt discontinuance of benzodiazepines (including convulsions, tremor, abdominal and muscle cramps, vomiting and sweating). Addiction-prone individuals e.g. drug addicts and alcoholics, should be under careful surveillance when on benzodiazenines because of their predisposition to habituation and dependence. Withdrawal symptoms have also been reported following abrupt discontinuance of benzodiazepines taken continuously at therapeutic levels for several months

Precautions: In depression accompanying anxiety, consider possibility for suicide

For elderly or debilitated patients, initial daily dosage should not exceed 2mg to avoid oversedation Terminate dosage gradually since abrupt withdrawal of any antianxiety agent may result in symptoms like those being treated: anxiety, agitation, irritability, tension, insomnia and occasional convulsions. Observe usual precautions with impaired renal or hepatic function. Where gastrointestinal or cardiovascular disorders coexist with anxiety, note that lorazepam has not been shown of significant benefit in treating gastrointestinal or cardiovascular component. Esophageal dilation occurred in rats treated with lorazepam for more than 1 year at 6mg/kg/day. No effect dose was 1.25mg/kg/day (about 6 times maximum human therapeutic dose of 10mg/day). Effect was reversible only when tre was withdrawn within 2 months of first observation. Clinical significance is unknown; but use of lorazepam for prolonged periods and in geriatrics requires caution and frequent monitoring for symptoms of upper G.I. disease. Safety and effectiveness in children under 12 years have not been

ESSENTIAL LABORATORY TESTS: Some patients have developed leukopenia; some have had elevations of LDH. As with other benzodiazepines, periodic blood counts and liver function tests are recommended during long-term therapy.

CLINICALLY SIGNIFICANT DRUG INTERACTIONS: Benzodiazepines produce CNS depressant effects when administered with such medications as barbiturates or alcohol.

CARCINOGENESIS AND MUTAGENESIS: No evidence of carcinogenic potential emerged in rats during an 18-month study. No studies regarding mutagenesis have been performed

PREGNANCY: Reproductive studies were performed in mice, rats, and 2 strains of rabbits, Occasional anomalies (reduction of tarsals, tibia, metatarsals, malrotated limbs, gastroschisis, malformed skull and microphthalmia) were seen in drug-treated rabbits without relationship to dosage. Although all these anomalies were not present in the concurrent control group, they have been reported to occur randomly in historical controls. At 40mg/kg and higher, there was evidence of fetal resorption and increased fetal loss in rabbits which was not seen at lower doses. Clinical significance of these findings is not known. However, increased risk of congenital malformations associated with use of minor tranquilizers (chlordiazepoxide, diazepam and meprobamate) during first trimester of pregnancy has been suggested in several studies. Because use of these drugs is rarely a matter of urgency, use of lorazepam during this period should almost always be avoided. Possibility that a woman of child-bearing potential may be pregnant at institution of therapy should be considered. Advise patients if they become pregnant to communicate with their physician about desirability of discontinuing the drug. In humans, blood levels from umbilical cord blood indicate placental transfer of lorazepam and its glucuronide.

NURSING MOTHERS: It is not known if oral lorazepam is excreted in human milk like other benzodiazepines. As a general rule, nursing should not be undertaken while on a drug since many drugs are excreted in milk

Adverse Reactions, if they occur, are usually observed at beginning of therapy and generally disappear on continued medication or on decreasing dose. In a sample of about 3,500 anxious patients, most frequent adverse reaction is sedation (15.9%), followed by dizziness (6.9%), weakness (4.2%) and unsteadiness (3.4%). Less frequent are disorientation, depression, nausea, change in appetite, headache, sleep disturbance, agitation, dermatological symptoms, eye function disturbance, various gastrointestinal symptoms and autonomic manifestations. Incidence of sedation and unsteadiness increased with age. Small decreases in blood pressure have been noted but are not clinically significant, probably being related to relief of anxiety.

Transient amnesia or memory impairment has been reported in association with the use of benzodiazepines.

Overdosage: In management of overdosage with any drug, bear in mind multiple agents may have been taken. Manifestations of overdosage include somnolence, confusion and coma. Induce vomiting and/or undertake gastric lavage followed by general supportive care, monitoring vital signs and close observation. Hypotension, though unlikely, usually may be controlled with Levarterenol Bitartrate Injection U.S.P. Usefulness of dialysis has not been determined



DOSAGE: Individualize for maximum beneficial effects. Increase dose grawhen needed, giving higher evening dose before increasing daytime doses. Anxiety, usually 2-3mg/day given b.i.d. or t.i.d.; dosage may vary from 1 to 10mg/day in divided doses. For elderly or debilitated, initially 1-2mg/day; insomnia due to anxiety or transient situational stress, 2-4mg h.s.

HOW SUPPLIED: 0.5, 1.0 and 2.0mg tablets.



In addition to effective relief of anxiety associated with depressive symptoms...

among leading benzodiazepines, has proof that its pharmacokinetics are not significantly altered by age.1

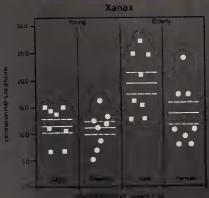
With Ativan, elimination half-life was very similar between young and elderly groups tested: differences did not approach statistical significance.1

Comparison of elimination half-lives in young and elderly subjects.



Ativam (lorazepam)²
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Xanax® (alprazolam)³ CIV
Xanax® requires oxidative
(P450) metabolism, significant
differences in half-life are shown
between young and elderly
male subjects; half-life is minimally
influenced by age in women.

- References:

 1. Greenblatt DJ: Clinical study, pharmacokinetics and bioavailability in the elderly, Ativan[®] (lorazepam). Data on file, Wyeth Laboratories

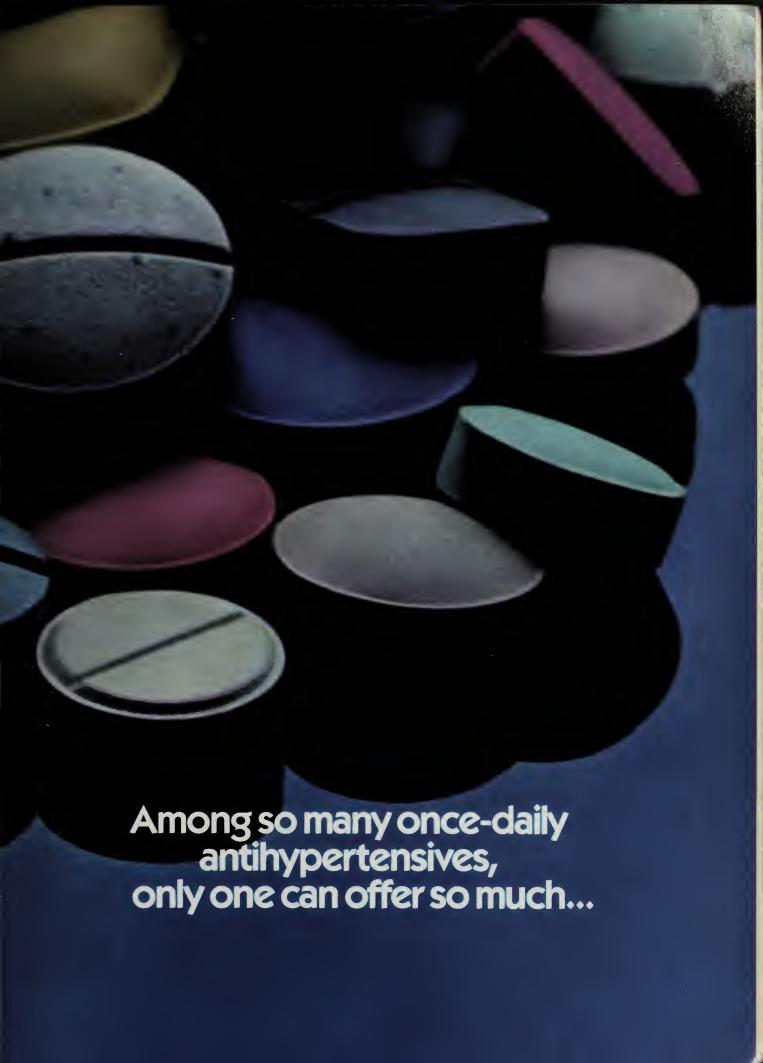
 2. Greenblatt DJ, Allen MD, Locniskar A, et al: Lorazepam k nebcs in the elderly. Cl. Pharmacol Ther 26:103, 1979

 3. Greenblatt DJ. Divol, M. Abernethy DR, et al. A prazolam k netics in the elderly. Arch Gen Psychiatry 40:287, 1983



See important information on preceding page

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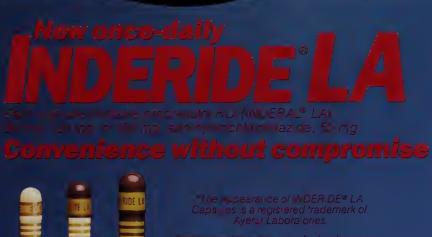
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INDERIDE LA is indicated in the management of hypertension

This fixed-combination drug is not indicated for initial therapy of hypertension. If the fixed combination represents the dose titrated to the individual patient's needs, therapy with the fixed combination may be more convenient than with the separate components.

CONTRAINDICATIONS

Propranolol hydrochloride (INDERAL*):

Propranolol is contraindicated in 1) cardiogenic shock 2) sinus bradycardia and greater than lirist degree block, 3) bronchial asthma. 4) congestive heart failure (see WARNINGS) unless the lailure is secondary to a tachyarrhythmia treatable with propranolol.

Hydrochforothiazide:

Hydrochlorothiazide is contraindicated in patients with anuria or hypersensitivity to this or other sulfonamide-derived drugs

WARNINGS
Propranolol hydrochloride (INDERAL*):
CARDIAC FAILURE Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure if necessary they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE continued use of beta blockers can in some cases, lead to cardiac failure. Therefore at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranolol should be discontinued (gradually if possible).

IN PATIENTS WITH ANGINA PECTORIS there have been reports of exacerbation of angina IN PATIENTS WITH ANGINA PECTORIS there have been reports of exacerbation of angina and in some cases myocardial infarction following abruto discontinuance of proprianolol therapy. Therefore, when discontinuance of proprianolol is planned the dosage should be gradually reduced and the patient carefully monitored in addition when proprianolol is prescribed for angina pectoris the patients should be Cautioned against interruption or cessation of therapy without the physician's advice. If proprianolol therapy is interrupted and exacerbation of angina occurs it usually is advisable to reinstitute proprianolol therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given proprianolol for other indications.

THYROTOXICOSIS Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism including thyroid storm. Propranolol does not distor thyroid function tests. IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME several cases have been reported in which after propranolol the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol. MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted however that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgicial procedures. and surgical procedures

Nonallergic Bronchospasm (eg. chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD. IN GENERAL. NOT RECEIVE BETA BLOCKERS INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors

DIABETES AND HYPOGLYCEMIA Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin. Hypoglycemic attacks may be accompanied by a precipitous ation of blood pressure

elevation of blood pressure
Hydrochlorothiazide:
Thiazides should be used with caution in severe renal disease. In patients with renal disease
thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects
of the drug may develop.
Thiazides should also be used with caution in patients with impaired hepatic function or
progressive liver disease since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.
Thiazides may add to or potentiate the action of other antihypertensive drugs.
Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma.
The possibility of exacerbation or activation of systemic lupus erythematosus has been
reported.

PRECAUTIONS

PRECAUTIONS
Propranolol hydrochloride (INDERAL*):
GENERAL Propranolol should be used with caution in patients with impaired hepatic or renal function Propranolol is not indicated for the treatment of hypertensive emergencies
Beta-adrenoreceptor blockade can cause reduction of intraocular pressure Patients should be told that propranolol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure
CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase alkaline phosphatase, lactate dehydrogenase
DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine, should be closely observed if propranolol is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

CARCINOGENESIS. MUTAGENESIS. IMPAIRMENT OF FERTILITY Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of lertility that was attributable to the drug.

PREGNANCY Pregnancy Category C. Propranolol has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximal recommended human dose There are no adequate and well-controlled studies in pregnant women. Propranolol should be used during pregnancy only if the potential benefit justifies the potential risk to the letus. NURSING MOTHERS Propranolol is excreted in human milk. Caution should be exercised when propranolol is administered to a nursing mother.

PEDIATRIC USE. Salety and effectiveness in children have not been established Hydrochlorothiazide:

Hydrochlorothiazide:
GENERAL Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance namely. Hyponatremia hypochloremic alkalosis and hypokalemia Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs irrespective of cause are Dryness of mouth thirst, weakness lethargy drowsiness restlessness muscle pains or cramps muscular latigue, hypotension oliguria tachycardia and gastrointestinal disturbances such as nausea and vomiting.

weakness lethargy drowsiness restlessness muscle pains or cramps muscular latigue. hypotension oligiuria tachycardia and gastrointestinal disturbances such as nausea and vomting. Hypokalemia may develop especially with brisk diuresis when severe cirrhosis is present or during concomitant use of corticosteroids or ACTH. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effect of digitalis (eg increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements such as foods with a high potassium content. Any chloride deficit is generally mild and usually does not redure specific treatment. except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatemia may occur in edematous patients in hot weather appropriate therapy is water restriction rather than administration of salt except in rare instances when the hyponatemia is life-threatening in actual sail depletion, appropriate replacement is the therapy of choice. Hyperuncemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy. Insulin requirements in diabetic patients may be increased decreased or unchanged Diabetes mellitus which has been latent may become manifest during thiazide administration if progressive erial impairment becomes evident, consider withholding or discontinuing duretic therapy.

Thiazides may decrease serum PBI, levels without signs of thyroid disturbance. Calcium excretions addresses about hiazides Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a lew patients on prolonged thiazide therap. The common complications of hyperparathyroidism, such as renal inhabits bone resortion, and peptic ulceration have not been seen. Thiazides should be discontinued beloe carrying our fests for parathyroid function. DRUG INTERACTIONS Thiazide drugs may increase the responsivenes

ADVERSE REACTIONS
Propranolol hydrochloride (INDERAL*):
Most adverse effects have been mild and transient and have rarely required the withdrawal of

Cardiovascular Bradycardia congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency usually of the

tension, paresthesia of hands, thrombocytopenic purpura, arterial insulinciency, usually of incernative depression progression manifested by insomnia, lassifude weakness, fatigue, reversible mental depression progressing to catatonia visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability slightly clouded sensorium, and decreased performance on neuropsychometrics. Gastronitestinal Nausea vomiting, epigastric distress, abdominal cramping diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis. Allergic Pharyngitis and agranulocytosis, erythematous rash fever combined with aching and sore throat Taryngospasm and respiratory distress. **Respiratory** Bronchospasm*** **Hematologic** **Agranulocytosis*** **nonthrombocytopenic purpura*** **Thrombocytopenic purpura****

Auto-Immune In extremely rare instances, systemic lupus erythematosus has been

Miscellaneous. Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impo-tence, and Peyronie's disease have been reported rarely. Oculomucoculaneous reactions involving the skin serous membranes, and conjunctivae reported for a beta blocker (practolol). ated with propranolol

Hydrochlorothiazide:

Irochiorothiazide: trointestinal. Anorexia. gastric irritation. nausea vomiting, cramping, diarrhea, constipa-jaundice (intrahepatic cholestatic jaundice), pancreatitis sialadenitis. Central Nervous System. Dizziness vertigo, paresthesias, headache xanthopsia. Hematologic Leukopenia agranulocytosis, thrombocytopenia apilastic anemia. Cardiovascular. Orthostatic hypotension (may be aggravated by alcohol. barbiturates, or pages.)

Hypersensitivity Purpura photosensitivity rash, urticaria necrotizing anglitis (vasculitis, cutaneous vasculitis), fever, respiratory distress, including pneumonitis, anaphylactic

reactions
Other Hyperglycemia, glycosuria hyperuricemia muscle spasm, weakness, restless-ness, transient blurred vision

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn

5112/985



LETTERS & VIEWPOINTS

Dangers of designer drugs

Designer drugs are looming as a new and potentially overwhelming threat in our efforts against drug abuse. Because of the nature of this problem and the impact it has on doctors, treatment center specialists, coroners and others in the medical field, I want to take this opportunity to bring it to the attention of The Journal of the Florida Medical Association, Inc.



Sen. Lawton Chiles

Designer drugs are chemical analogs of substances scheduled under the Controlled Substances Act (CSA). The term "designer drug" was coined by Dr. Gary Henderson of the University of California at Davis, who first became aware of the scope of this frightening new trend in drug abuse. Several years ago he found that clandestine chemists working in underground labs were producing a variety of these drugs and altering their chemical effects to suit the euphoric tastes and abusive desires of customers. Because the drugs vary slightly from the chemical formulas covered by the CSA, the chemist or user who is found to possess them cannot be prosecuted.

Designer drugs are extremely dangerous from a health standpoint. The drugs are thousands of times more potent than the illegal narcotics presently flooding this country. Over one hundred deaths have been attributed to designer drug use so far. Furthermore, these drugs have been linked to long term neurodegenerative diseases in some users. The human and medical economic costs of designer drugs are potentially devastating.

The designer drug phenomenon poses specific difficulties for those in the medical profession. Because the drugs are made in unregulated labs, each batch is likely to contain contaminants. One such case is being studied by Dr. J. William Langston, chairman of the neurology department of Santa Clara Valley Medical Center.

Dr. Langston has identified over 400 young people who took a designer variation of Demerol. Some of these users have symptoms identical to those exhibited by victims of Parkinson's disease. In synthesizing an analog of meperidine, 1-methyl-4-phenyl-4-proprionoxy-piperidine (MPPP), often 1-methyl-4-phenyl-1,2,5,6-tetrahydropyridine (MPTP) is made due to poor lab conditions. MPTP kills exactly the same brain cells which die when one has Parkinson's disease. Though some of these patients have responded to treatment using L-dopa, which is used to treat Parkinson's patients, this relief is only temporary.

Moreover, while most of the victims of MPTP contaminated drugs are currently asymptomatic, there are scientific reasons to fear that all of them may be at higher risk of developing a Parkinson's like condition in the future. In fact, a senior investigator at the National Institute of Health has referred to them as "walking time bombs." The cost of treatment and possible institutionalization of these people will be great. The terrible human cost of these young lives destroyed by designer drugs will be even greater.

Further, some designer drugs have been found to be as many as 7,000 times more powerful than morphine. Often the minute amounts that can be fatal are too small to be found in tests by medical examiners. Dr. Ronald K. Wright, Chief Medical Examiner of Broward Medical Examiners Office, wrote

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to me that designer drugs "are a nightmare for those of us charged with determining the causes of death of people who die suddenly and unexpectedly. The minute amounts capable of producing death are very hard to find. Thus, we suspect more deaths are occurring than are being reported." A statewide meeting of medical examiners in Florida in October will focus on designer drugs as medical examiners and law enforcement officials try to get ahead of the curve, try to stop the phenomenon of designer drugs before it gets to the disaster stage.

We need only remember the devastating effects of LSD in the 60's and PCP in the 70's to realize that the designer drug problem must be addressed now. I have been working during this Congress to focus national attention on the problem and to find solutions.

In March, I introduced legislation which required the National Drug Enforcement Policy Board to review the problem and make recommendations to Congress for necessary legislation. A short while later, I secured from Attorney General Meese a commitment to move expeditiously on the problem.

Then in July I held hearings in Washington which brought together Dr. Henderson, Dr. Langston, law enforcement officers from California and Florida and others involved in the designer drug phenomenon.

I am pleased to announce that as a result of these efforts, legislation which addresses the designer drug problem has been introduced in this Congress. In the Senate, S. 1437 would impose penalties of 15 years imprisonment and a \$250,000 fine to anyone convicted of manufacturing, distributing, or possessing with intent to distribute, any designer drug.

This is just the beginning of working toward a solution. I feel it is essential that medical professionals, law enforcement agencies, representatives from the pharmaceutical field, educators, and government officials work together in addressing this problem. Organizations like the Florida Pharmacy Association have worked to educate independent pharmacists about designer drugs and to make them aware of steps each can take to prevent being an innocent accomplice to a designer chemist's work. I encourage other groups to take similar action and would be pleased to provide assistance in such efforts.

The Honorable Lawton Chiles United States Senate Washington, D.C.



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Experience with routine thyroid function testing: abnormal results in "normal" populations

Kresimir Banovac, M.D., Margita Zakarija, M.D., and J. Maxwell McKenzie, M.D.

ABSTRACT: Thyroid function tests and prevalence of thyroid antibodies were studied in 586 blood donors and in a group of 135 normal pregnant women. Abnormal tests were found in approximately 8% of blood donors and 3.7% of pregnant women. Positive titers of antibodies to microsomal antigen occurred in 10% of blood donors and 9% of pregnant women. FT4 and FT3 concentrations in male subjects were significantly higher than in female (p< 0.001). Serum TBG concentration in women was $29.8 \pm 5.8 \,\mathrm{mg/L}$ which is significantly higher than $25.8 \pm 5.1 \,\mathrm{mg/L}$ in men (p<0.001). These data suggest that a significant number of blood donors have abnormalities of thyroid function tests and/or significant titers of thyroid antibodies, which may indicate need for more detailed thyroid function screening for determination of normal ranges for thyroid function tests.

The Authors KRESIMIR BANOVAC, M.D. MARGITA ZAKARIJA, M.D. J. MAXWELL McKENZIE, M.D.

Dr. Banovac is Assistant Professor, Dr. Zakarija is Professor and Dr. McKenzie is Professor of the Division of Endocrinology, Department of Medicine, University of Miami School of Medicine, Miami. This study was undertaken to determine the normal values of thyroid function tests for a routine thyroid laboratory using available commercial kits. We used bloods obtained from a group of clinic blood donors and from normal pregnant women attending a prenatal clinic.

Materials ● Five hundred eighty-six blood donors, 250 men and 336 women, consented to participate and 135 normal pregnant women also donated blood. The donors denied having acute or chronic illnesses but no detailed clinical evaluations were carried out. The pregnant women were considered by their obstetricians to be free of intercurrent medical disorders. The average age of the total group was 34 years for men (range 20-60) and 33 years for women (range 19-61).

Methods ● Serum was separated from clotted blood and stored at -20 C until used for the following assays: total and free thyroxine (TT_4 and FT_4), total and free triiodothyronine (TT_3 and FT_3), reverse triiodothyronine (rT_3), T_3 uptake test (T_3U), thyrotropin (TSH), thyroxine binding globulin (TBG), thyroglobulin antibody and antibody to the thyroid microsomal antigen. T_3U was used in conjunction with the serum T_4 determination to derive the Free Thyroxine Index (FTI).

The following commercial RIA kits were used in the study: T₄, T₃, TSH and T₃U from Becton-Dickinson, Immunodiagnostics, ARIA II System, Salt Lake City, Utah; thyroid microsomal antibody and thyroglobulin antibody test, Ames Division, Miles Labs., Elkhart, Ind. Serum FT₄ concentration was determined by use of a labeled T₄ analogue (Magic — single step FT₄ RIA — Corning), serum

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Table 1A. — Values of Thyroid Function Tests in Blood Donors.								
Subjects	Age	T₄ ug/dl	T₃ ng/dl	rT₃ ng/dl	T₃U %	FTI		
Male	33.7 ± 9.8*	7.1 ± 1.1	149 ± 24	22.2 ± 5.7	30.6 ± 2.9	7.2 ± 1.1		
Range	20 - 60	4.8 - 10.9	83 - 222	14.6 - 35.1	24.1 - 38.2	4.9 - 11		
n	250	246	263	25	246	247		
Females	33.1 ± 10.8	7.6 ± 1.3**	137 ± 24**	20.7 ± 4.8	28.9 ± 2.8**	7.3 ± 1.1		
Range	20 - 61	4.6 - 10.6	88 - 208	12.3 - 37.7	23.0 - 36.6	4.2 - 10.1		
n	336	296	297	82	296	296		
Total	33.4 ± 9.9	7.4 ± 1.2	143 ± 2.4	21.2 ± 5	29.7 ± 2.9	7.2 ± 1.1		
Range	20 - 61	4.6 - 10.9	83 - 222	12.3 - 37.7	23 - 38.2	4.2 - 11		
n	586	542	560	106	542	543		

FT₃ concentration by Amerlex Free T₃ kit (Amersham) using a ¹²⁵I-labeled deritive of T₃. Serum TBG and reverse T₃ concentrations were measured by radioimmunoassay, Serono Diagnostics, Inc., Braintree, Mass.

For all procedures we followed the manufacturers' recommendations precisely and used the standards provided. All sera were analyzed in duplicate. Control sera with low T_4 , T_3 , and normal TSH concentrations and elevated T₃U value were from Becton Dickinson Immunodiagnostics. A pool of sera obtained from normal pregnant women was used as a standard with an elevated T4 and T3, and low T₃U value. The data were transferred to punch cards that were then processed using the HESM31 528 Univac 1100 program. Evaluation of statistical significance of differences was by "t" testing with a 95% limit of significance. The intraassay coefficient of variation (CV) for the control serum (80 assays) was 0.85% for T_4 , 3.2% for T_3 , and 1.6% for TSH. The interassay CV was calculated for standards with decreased and elevated T4 and T3 concentration, normal and elevated TSH concentration and low and high T₃ uptake values; for low and high T₄ this was respectively 4.4% and 3.8%, for T₃ 10.3% and 7%, and for T₃U 3.1% and 3.5%. The interassay CV for sera with high and normal TSH concentrations was 15.7% and 15.4% respectively. The quality control studies for the thyroid function tests were part of the Proficiency Testing Program of the Center for Disease Control, Department of Health and Human Services, Atlanta Ga., and the Interlaboratory Comparison Program, College of American Pathologists, Skokie, Ill.

Results • Table 1A lists the values of thyroid function tests in blood donors; normal values may thus be defined as shown in Table 1B. The mean serum T_4 concentration was higher in women than in men (p < 0.0001), while the mean T_3 concentration and T_3U were higher in male than in female donors (p < 0.001). There was no statistical difference in FTI values between these two groups.

For pregnant women, Table 2 summarizes typical results, i.e., elevated total T_4 and T_3 and TBG in addition to a decrease of T_3U . In this group a maximal individual value of serum T_4 concentration was 16.7 ug/dl, for T_3 254 ng/dl and for TBG 69.9 mg/l. However, the range of FTI was similar to that found in normal nonpregnant subjects.

Serum FT_4 and FT_3 concentrations were significantly higher in normal male blood donors than in females (p<0.001); serum TBG was lower in males than in females (p<0.001) (Table 3).

Table 4 shows the values of serum TSH concentrations in blood donors. TSH was unmeasurable (<0.5uU/ml) in approximately 15% of both females and males; in 95% the TSH concentration was less that 3.5 uU/ml and 5.2 uU/ml was the highest value observed.

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Table 1B. — Normal Values for Thyroid Function Tests. T₃U FTI T₄ ug/dl T₃ ng/dl rT₃ ng/dl % 143 21.2 29.7 7.2 Mean 7.4 5 - 9.8 91 - 215 11.2 - 31.2 23.9 - 35.5 5.0 - 9.4± 2 SD 12.3 - 37 23 - 38.2 4.2 - 11Range 4.5 - 10.983 - 222

Т	Table 2. — Values of Thyroid Function Tests in Normal Pregnant Women.								
	T₄ ug/dl	T₃ ng/dl	T ₃ U %	FTI	TBG mg/L				
n	255	135	135	135	100				
Mean ± SD	10.9 ± 1.9	186 ± 28.8	16.7 ± 2.4	6.1 ± 1.1	54.5 ± 8.5				
Range	6.1 - 16.3	131 - 254	11.4 - 23.5	3.8 - 9.7	32.2 - 69.9				

A positive test for antithyroglobulin (>1:10) was found with only five sera; all five were also positive (>1:400) for antibody to the microsomal antigen. Therefore data for only the latter antibody are given (Table 5). Of all blood donors 10.7% were positive; the prevalence was higher in females (15%) than in males (5%). When the age distribution of subjects with positive antibodies was analyzed, 75% of males and 88% of females were in the younger age group (20-40 years) (Table 6).

Abnormal thyroid function tests were found in 8% of the blood donors (47 of 586 subjects) (Table 7). These were of three types of data, viz., low T_3U with high T_4 (all female, 12% of 336); high T_3U and low T_4 (four men, i.e., 1.6% of 250); one female and two males, all with serum positive for antibody to the microsomal antigen, had TSH above normal.

Discussion ● The primary intent of this study was to establish normal values of thyroid function tests for a routine laboratory using sera from a group of blood donors. These are listed in Table 1. Analysis of the data showed significant differences between mean values of TT₄, TT₃ and T₃U in females and males although the differences were small and clinically irrelevant. This finding of statistical significance is a characteristic of analysis of large samples.¹ Similarly FT₄ and FT₃ differed between the two sexes, males having higher mean values while they had a TBG concentration significantly lower. The reason for the difference in free thyroid hormone concentrations is unknown, but it has

been previously reported by analog T₄ RIA determination.² Furthermore, earlier studies described higher TBG levels in women than in men³ and whether such findings can explain the differences in FT₄ and FT₃, or whether they are of physiological importance, is unknown.

Although the prevalence of abnormal thyroid tests in a general population is uncertain, in this report we call attention to the fact that 8% of 586 blood donors had one or more abnormality and that 10% had positive thyroid antibodies. As Tables 3 and 4 show, several alterations of thyroid function tests occurred. The abnormal serum total T4 concentration and T₃U were in approximately 8% of subjects, the majority having an elevation of T₄ with a low T_3U and the rest a low T_4 and high T_3U . Although clinical data are missing for the accurate interpretation of these results, it is most likely that the alterations can be attributed to changes in TBG. All 40 subjects with elevated total T₄ and low T₃U were young females in whom an increase in TBG due to estrogen administration is highly likely. In contrast, in four men there was a low T4 and high T₃U compatible with TBG deficiency. A low concentration of TBG occurs in several clinical syndrome such as hypoproteinemia,4,5 androgen therapy, 6 or secondary to hereditary factors; 7 any of these causes may have been operative in the four men we identified.

Thyroid antibodies occur in the serum of patients with Hashimoto's thyroiditis or Graves' disease but also in patients with subacute thyroiditis,

Table 3. — Free Thyroid Hormone Concentrations and TBG in Blood Donors. FT₄ FT₃ TBG ng/dl Subjects pg/ml mg/L Males $2.1 \pm 0.4*$ 5.1 ± 0.9 25.8 ± 5.1 1.24 - 2.56 18.3 - 46.1 2.98 - 6.44 Range 35 27 99 1.8 ± 0.2** $4.2 \pm 0.7**$ 29.8 ± 5.8** Females 18.9 - 47.2 1.2 - 2.42 2.5 - 6.3 Range 107 132 109 n 4.4 ± 0.8 27.9 ± 5.8 Total 1.9 ± 0.3 1.2 - 2.96 2.5 - 6.44 18.3 - 47.2 Range 144 134 221

thyroid carcinoma or after thyroid surgery or therapy with radioiodine.⁸ Previous studies on blood donors by Bjoro et al showed a prevalence of antibodies to thyroglobulin of 3.4% and to the microsomal antigen of 7.0%.⁹ Similarly, we found 10.7% of blood donors with positive thyroid antibodies with the higher prevalence being in females and in the younger age groups (Table 5). There is evidence that the peak prevalence of thyroid antibodies reflecting autoimmune thyroid disease occurs between the age of

*Mean ± SD

**p < 0.001 males vs females

Table 4. — Serum TSH in Blood Donors.								
	TSH (uU/ml)							
	0.5	0.6 - 3.5	3.6 - 5.2*					
Males	32	176	7					
n=215	15%	82%	3%					
Females	44	229	7					
n=280	15%	82.5%	2.5%					
Total	76	405	14					
n=495	15.3%	82%	2.5%					
*5% relative frequency								

Table 5	Prevalence of Thyroid Antibodies in 383 Blood Donors.			
	n	%		
Males	8	5		
Females	33	15		
Total	41	10.7		

Table 6. — Age Distribution of Subjects with Positive Antithyroid Antibodies.

Blood Donors									
		MALES			FEMALES		MA	LES + FEMA	LES
Age Group	No.	Ab+ve	%	No.	Ab+ve	%	No.	Ab+ve	%
19-20	4	0	0	4	1	25.0	8	1	12.5
21-30	101	5	5.0	99	15	15.2	200	20	10.0
31-40	27	1	3.7	81	14	17.3	108	15	13.9
41-50	16	1	6.3	21	2	9.5	37	3	8.1
51-60	11	1	9.1	15	1	6.7	26	2	7.7
61-65	3	0	0	1	0	0	4	0	0
Total	162	8	4.9	221	33	14.9	383	41	10.7

Ab = Microsomal antigen Titer 1:1600 and up

Table	7.	_	Prevalence of Abnormal Thyroid
			Function Tests in 586 Blood Donors.

	Females	Males
Elevated T ₄	40	0
with low T ₃ U	6.8%	0
Low T ₄ with	0	4
elevated T ₃ U	0	0.7%
Elevated TSH*	1	2

*Individual results: 7uU/ml; 9.1 uU/ml and 14 uU/ml; all patients antithyroid antibodies positive.

50 to 60 years; 10 our finding of more positive results in the younger population may be attributable to the small number of older participants in this study.

It is generally accepted that the majority of the available techniques for the measurement of serum TSH have poor sensitivity for the lower limits of the normal range. In this study of euthyroid subjects we failed to detect TSH in 15.3% of subjects and the upper limit was approximately 3.5uU/ml (in 95% of subjects, Table 4). An elevation of serum TSH was seen in 0.5% of subjects and in these there were also positive thyroid antibodies. Since the serum TSH concentration is the most sensitive indicator of thyroid failure, it may be assumed that the mild elevation of serum TSH and positive antibodies in these patients represent subclinical hypothyroidism.

In conclusion our results in blood donors suggest that a comprehensive evaluation of thyroid function tests and a screening of thyroid antibodies

are necessary to establish the normal range of values since 8% of presumably euthyroid subjects have abnormalities in routine tests.

Acknowledgment

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Aberrant right subclavian artery as a cause of respiratory distress and dysphagia in an adult

Eduardo Chapunoff, M.D., F.A.C.P., F.A.C.C. and Irwin B. Boruchow, M.D.

ABSTRACT: A 27-year-old female presented with a long history of severe attacks of respiratory distress and dysphagia. The physical examination, ECG, chest x-ray and echocardiogram were normal. A barium esophagram disclosed a characteristic indentation due to an aberrant right subclavian artery. Esophageal-tracheal compression may be related to the concomitant existence of an abnormal origin of the carotid arteries. Following corrective surgery, the patient became asymptomatic.

In 1794 Bayford described the autopsy of a 62-yearold woman who was emaciated and had experienced dysphagia for 20 years. The esophagus was obstructed by an anomalous right subclavian artery. He termed the condition "dysphagia lusoria." The Latin word lusor means deceiver, a freak of nature.

In 1945 Gross first successfully divided the artery in an infant with good results.

This has been described as the most frequent anomaly of the aortic arch (.5 to 1% of population).¹ Usually it is asymptomatic. In symptomatic patients, a double aortic arch appears to be the most frequent abnormality. In childhood, an aberrant right subclavian artery can cause serious respiratory and swallowing difficulties. Adults, almost always, suffer from dysphagia alone.² This report describes the occurrence of dysphagia and respiratory distress in an adult with that abnormality.

Case report — A 27-year-old white female presented with a chief complaint of intermittent episodes of shortness of breath. She also gave a long history of difficulties in swallowing manifested by a feeling of food being stuck in the upper third of her chest. During infancy she "would choke and turn blue." During adolescence and adulthood she continued to have sporadic bouts of severe dyspnea, at times associated with moderate cyanosis. Dysphagia was a more frequent but generally less distressing symptom. She saw different physicians but a definitive diagnosis was never reached. During the week preceding admission to the hospital, she had alarming attacks of dyspnea. Her physical examination, ECG, chest x-ray and echocardiogram were normal. The barium esophagram (Fig. 1) showed a posterior indentation in the upper third of the esophagus. A retrograde aortogram confirmed an anomalous origin of the right subclavian artery originating from the descending thoracic arch. The two common carotids orginated from a single trunk.

The Authors

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Fig. 1. — Preoperative barium esophagram showing indentation in the upper third of the esophagus with severe constriction.

Because of the severe nature of the symptomatology, surgery was recommended. The right chest was opened through a 4th interspace incision. The aortic arch was on the left side. The subclavian artery was divided and an 8 mm Gortex graft was sutured end-to-end to the artery and end-to-side to the ascending aorta. The postoperative course was uneventful. Four years following surgery the patient remains asymptomatic and the barium esophagram is normal (Fig. 2).

Discussion ● Vascular rings are aortic arch anomalies which may cause tracheal and esophageal compression. Clinically the three most important types are double aortic rings, right aortic arch with short left ductus arteriosus (ligamentum), and retroesophageal right subclavian artery. Patients with vascular rings are usually symptomatic during infancy and childhood with symptoms most frequently involving the respiratory tract. Dysphagia is less frequent. Respiratory manifestations include stridor, wheezing, cough, episodic choking, cyanosis, aspiration, respiratory infection and death by complications of respiratory obstruction.³ The few symptomatic adults with an aberrant right subclavian artery nearly always complain of only

dysphagia. Rarely, an arteriosclerotic aneurysm of an upper mediatinal shadow on the chest radiograph.⁴ The anomalous right subclavian artery graph.⁴ The anomalous right subclavian artery originates as the last branch of the aortic arch beyond the left subclavian artery and follows a left to right course to reach the right thoracic outlet. This situation usually produces no symptoms. On occasions, symptoms may be dramatic.³ Klinkhamer² proposed that the combination of an aberrant right subclavian artery and an abnormal origin of the carotid arteries is required for occurrence of compression and production of symptoms. This may explain why the sole presence of the artery lying behind the esophagus and well fixed between



Fig. 2 — Postoperative barium esophagram showing resolution of the previously constricted area.

the rigid vertebral column behind and the trachea in front is enough in some cases to produce compressive symptomatology.⁵

Normally the innominate artery and the left carotid artery originate from the arch at a distance of about 4 cm from each other. Consequently, when an aberrant right subclavian artery presses the esophagus (and the trachea), this space is utilized; the esophagus and the trachea can bend forward and no compression occurs. However, when the two carotids are situated closer to each other or there is a common origin of the right and left carotid arteries (bicarotid truncus arteriosus, as in our patient), a V-like structure is formed and the trachea is prevented from bending forward. It is noteworthy that among 292 cases collected from the literature by Klinkhamer (76 publications), a bicarotid truncus arteriosus or a close origin of the carotids was found in 116 (36%) and symptoms and signs of tracheoesophageal compression were only present in these cases. This suggests that in the majority of symptomatic patients with an aberrant right subclavian artery the described abnormal disposition of the carotids would be responsible for the compressive symptomatology. The reasons for the episodic nature of the symptoms, however, are far from clear.

The simplest way of reaching a diagnosis is by barium esophagram which shows a characteristic oblique posterior indentation in the upper third of the esophagus (Fig. 1). More precise information on aortic vascular rings can be obtained by angiographic procedures (conventional arteriography and intravenous digital subtraction angiography.^{6,7}

Division of the artery is indicated in symptomatic patients. In infants, delays have led to catastrophes.³ In children, division of the artery is all that is required; however, in adults, reestablishment of blood flow to the subclavian artery is the treatment of choice.⁸ Transection of the subclavian artery in the adult without reimplantation in the

aorta can lead to ischemic right upper extremity symptoms and a subclavian steal syndrome of varying severity. The case presented indicates that adults with an aberrant right subclavian artery may have severe attacks of dyspnea. It also suggests that long standing paroxysmal attacks of respiratory distress and dysphagia associated with normal physical examination, electrocardiogram and chest x-ray should invite the exclusion of a vascular ring abnormality, of which, in the adult, an aberrant right subclavian artery would be the most likely cause.

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Computerized tomography and electroencephalography in childhood coma: which test should be performed first?

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ABSTRACT: The evaluation of the comatose child often requires use of computerized tomography of the brain and electroencephalography. The results of CT scans of the brain in 56 and EEGs in 44 patients were reviewed to determine their value and the order in which they should be performed. We suggest that when both tests are being considered on a given patient the CT scan should precede the EEG in patients with head trauma and in those whose etiology has not been established and that the EEG should precede the CT scan in patients with an established etiology for coma other than head trauma.

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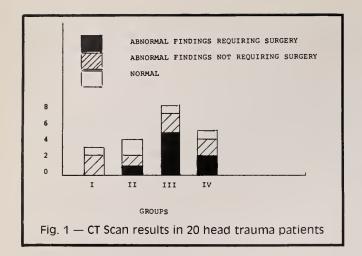
Evaluation of the comatose child often requires the use of computerized tomography of the brain and electroencephalography. The purpose of this study is to determine the order of these tests.

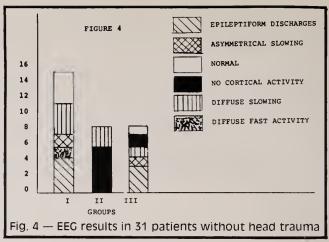
Methods and results ● There are many definitions of coma^{1,2} but for the purposes of this study it is defined as a state of altered mental status with a severe deficit of the arousal mechanism. In this study all patients had an acute or subacute onset of sleep-like state. They were either unarousable to deep painful stimuli or, if aroused, were confused and drifted back to a sleep-like state when the stimulus was discontinued. None were aroused by verbal stimulation.

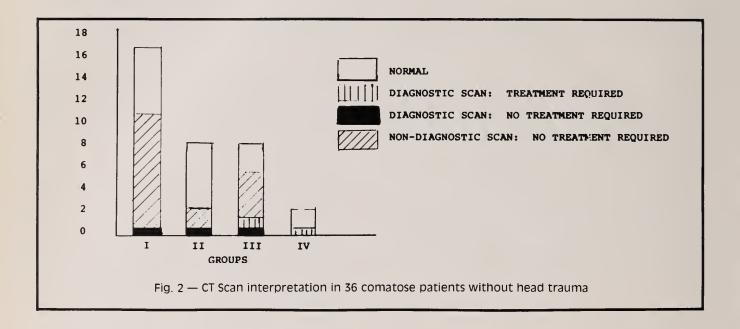
One hundred one comatose children aged five weeks to 15 years hospitalized consecutively in Jackson Memorial Hospital from June 1979 to April 1982 constituted the study population. The distribution according to age groups was as follows: one to 12 months, 26 patients; 12 to 26 months, 27 patients; 36 to 72 months, 22 patients, and 72 months to 15 years, 26 patients. There was a male predominance of 56 vs 45 with twice as many males having suffered head trauma. The most frequent cause of coma was head trauma followed by metabolic disorders and poisoning (Table 1). Intracranial infection was found in 14% of our nontrauma patients. Seven patients had no established etiology after a thorough clinical and laboratory examination which included a spinal tap. After a CT and/or an EEG the etiology was established for all but one of

The patients were divided into four groups according to the initial neurological examination performed by a pediatric neurologist, neurosurgeon or a

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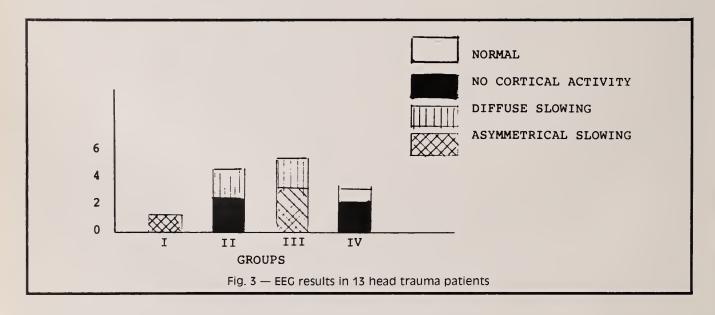


Table 1.—Etiologic Diagnosis of 101 Comatose
Patients and Correlation to the Neurological Classification

	Total	1	II	Ш	IV
Metabolic	23				
Hepatic	8	5	3		
Renal	4	2		2	
Endocrine	2	2			
Fluid and Electrolyte	7	7			
Other	2	1	1		
Trauma	24	4	6	8	6
Poisoning	13	12	1		
CNS Infection	11				
Bacterial	5	3		1	1
Viral	6	4		2	
Cardiorespiratory Arrest	8	2	3	3	
Septicemia	7	5	2		
Near Drowning	6	1	5		
Cerebral Vascular Accident	3	1	1	1	
Seizure	3	2		1	
Intracranial Tumor	2			1	1
Unknown	1	1			
	101	52	22	19	8

Table 2. — Groups According To Neurological Examination.

Groups	Brainstem Deficit	Supratentorial Lateralization
1	0	0
ll l	+	0
III	0	+
IV	+	+

pediatric intensivist. The groups were determined by the presence or absence of brainstem abnormalities and or lateralizing cerebral deficits (Table 2). The relation between the different etiologies and the neurological classification is shown in Table 1. The results of the CT scans in 56 patients and EEGs in 44 were considered in the light of this classification as well as two major etiological subdivisions: traumatic and nontraumatic. Figures 1 and 2 correlate the CT scan results with the need for therapy in trauma and its contribution to the etiological diagnosis in nontraumatic coma patients. Figures 3 and 4 indicate the EEG findings based on the same premises in these same two categories (trauma vs nontraumatic coma). All these figures are also correlated with the neurological classification.

Discussion ● The diagnostic capability of the CT in the evaluation of head trauma cannot be overemphasized.³⁻⁵ Of 24 patients with head trauma, 20 had CT scans (Fig. 1) eight required surgery. Of the four groups, patients in group III required surgery more frequently. Though none of the patients in group I required surgery, in two of the three surgery was considered as a therapeutic measure. Their CT scan did not alter managemnt of 15 patients with an established etiology; it was diagnostic in 5 of 7 patients without one.

EEGs did not alter management of the comatose head trauma patient except in cerebral death determination (Fig. 3). The EEG was very useful in the evaluation of the nontraumatic comatose patient (Fig. 4). Epileptiform activity was present in seven of 31 patients in this group. In contrast to the CT scan the EEG was most valuable in those patients with an established etiology. Epileptiform activity was detected in six of the 26 of these patients while only in one of the seven patients whose etiologic diagnosis had not been established.

In summary we believe that a CT scan should be performed prior to the EEG in patients with head trauma and on those with an undetermined etiology for the comatose state. The EEG should precede the CT scan in nontrauma patients with an established etiology. The neurological examinations were not a good indicator as to which should be performed first.

Acknowledgement

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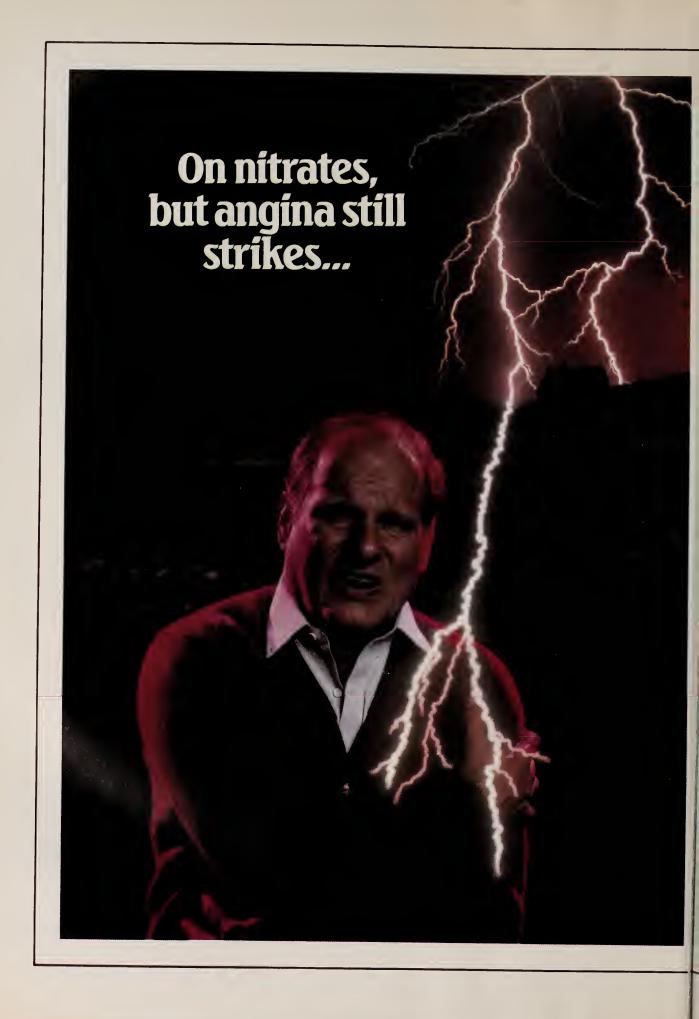
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Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment; however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W-P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN. Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradveardia may occur. High grade block however has been and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rarely, discontinuation and institution of appropriate therapy depending upon the clinical situation. Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high morable that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including sinus bradycardia, 2° AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. **Precautions:** ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over- or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. *Pregnancy Category C*: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. Adverse Reactions: Hypotension (2.9%), peripheral edema (1.7%), AV block: 3rd degree (0.8%), bradycardia: HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported. (See *Warnings*.) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation. **How Supplied:** ISOPTIN (verapamil HCl) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochloride and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLL" on the reverse side. Revised August, 1984



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SPECIAL ARTICLES

Present status of scoliosis screening in Florida schools

Joseph C. Flynn, M.D., Max F. Riddick, M.D., Charles T. Price, M.D., and Thelma L. Keller, P.T.

ABSTRACT: Statewide screening of Florida school children for early detection of spinal deformity is now established in grades 6 to 9. In three years, nearly a half million (496,965) examinations have been done. The incidence of possible spinal curvatures in these children is 6% (32,368). Our history of screening is recounted. The errors and pitfalls have been located and discussed. The routine screening of Florida school children for spinal deformity is practical and effective.

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The advantage of early detection of spinal detormity in growing children is that it can often be arrested before becoming severe. At the least, this will spare the child a serious, painful and expensive operation and, at the most, a lifetime of compromise because of appearance, limited function and pain.

History of scoliosis screening in Florida • The routine examination of school children for spinal deformity (scoliosis screening) originated nearly 20 years ago in Delaware and has been successful in virtually eliminating the need for surgery for idiopathic scoliosis in that state.¹

Scoliosis screening in Florida began with a pilot program in Orange County schools in 1975.2 This program was supported by the Citrus Orthopaedic Society and Florida Orthopaedic Society and had the approval of the Orange County Medical Society. Primary screening was done by physical education teachers who had been trained by an orthopaedistphysical therapist team. Secondary screening was done by volunteer orthopaedic surgeons of the Citrus Orthopaedic Society. The idea quickly spread to surrounding counties and with the help of the Florida Orthopaedic Society to more remote counties. Doctors, nurses, physical therapists, parents, and school authorities in numerous counties cooperated to spread screening across the length and breadth of Florida.

It became evident that a statewide program, to be a reproducible model year after year in all 67 counties, could not depend on volunteer orthopedists (some counties had few or none). We turned to Citrus and Hernando Counties where the school or county health nurse replaced the doctor. The suc-

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cess of the program in those two counties served as a further model that would be practical for all 67 counties.

Meanwhile, the School Health Advisory Committee of the Florida Medical Association gave its support to scoliosis screening. This Committee is composed of physicians and key personnel from the Department of Health and Rehabilitative Services in School Health and Family Health as well as personnel from the Department of Education.

In 1979 the Florida legislature mandated scoliosis screening for the early detection of spine deformity in Florida school children.

The Health and Rehabilitative Services Committee of the Florida House of Representatives studied the need for scoliosis screening by questioning medical witnesses and reviewing the pilot Orange County program. Individual legislators responded to the request of Florida Orthopaedic Society and Florida Medical Association members by introducing and supporting the necessary amendment.

In 1979 the Florida legislature mandated scoliosis screening for the early detection of spine deformity in Florida school children. Section 402.32, Florida Statutes, 1978 Supplement, was amended on July 1, 1979 to read: "School Health Services Program. . . (5) Each District School Board and the Department of Education where applicable shall have the duty of: (f) To examine each public school child, at the proper age, for scoliosis." In 1980 the legislature included private schools in the mandate for scoliosis screening.

Ten year screening statistics for Orange County are shown in Table 1. The screening was done in 20 junior high schools, grades 7 to 9. In the first four years suspected curves were seen in 1.6% of students screened. In the next six years, 2.4% were referred

with suspected scoliotic curves. The ratio of girls to boys was 2:1. Orthopaedic surgeons screened for the first seven years. Nurses have screened since 1982. Note that the number of suspected curves rose sharply nearly doubling the first year, then gradually declined as nurse-screeners gained more experience. The number of cases under treatment is not recorded until 1979. Note that the number is steadily decreasing and the ratio of girls to boys is approximately 4:1.

The initial statewide screening was done in the appropriate junior high schools, grades 7, 8 and 9 or grades 6, 7 and 8 in those counties with middle schools. The first year of statewide screening in 1979 to 1980, 49 of 67 counties reported 70,503 children screened with 5,664 (8%) referred for evaluation for possible scoliosis; 1,571 (2%) were placed under treatment or observation (Table 2).3,4

Statistics for 1981-82 reporting by district (1 to 11) rather than county (Table 3) showed that 235,131 children were screened. Of these, 5% (11,835) were referred for examination and 87% (10,271) completed the evaluation by a physician.

For 1982-83, our third year of screening, (Table 4) 191,331 children were screened. The nurse-screener referred 8% (15,272) for further examination; 15,176 completed the suggested examination by a physician. Unfortunately, we do not have statistics of numbers requiring treatment by observation, brace or surgery.

We are now in our fourth year of statewide screening and state officials are considering streamlining the screening program by selecting one grade, i.e., grade 6 or 7.

Table 5 shows the number of children in various grades 6 to 9 across the state. We believe that screening should continue in 7th and 8th grades (ages 13 and 14) and in those counties having junior high schools. Likewise, it should continue in grades 6 and 7 in those counties having middle schools. If, however, we were forced to select one grade only, it would be the 7th grade. Seventh graders are between

Table 1. — Scoliosis Screening Statistics, Orange County Schools*

YEAR	NUMBER SCREENED	Number	REFERRED Percent	Girls	Boys	TREATM Girls	MENT** Boys	NON PARTICIPANTS
1975-1978	64,906	1,086	1.6	746	340	_	_	_
1979	15,188	138	0.9	94	44	7	1	_
1980	16,880	355	2.1	243	112	97	35	252
1981	16,366	264	1.6	188	76	88	28	380
1982	16,376	619	3.7	384	235	61	14	297
1983	14,636	524	3.5	341	183	78	8	394
1984	13,299	383	2.8	246	137	62	13	411

^{*20} schools screened grades 7-9

^{**}Observation, lateral electrical spine stimulation, brace, surgery

Table 2. — Florida Screening 1979-80, Grades 6-9, 49 of 67 Counties.

To	tal
Screened	03
Number Referred	%)
Number Treated	%)

Table 3. — Florida Screening 1981-82, Grades 6 to 9, 11 Districts, 67 Countries.

Screened	131
Referred	5%)
Completed	271

12 and 13 years of age and have two or more years of skeletal growth ahead of them.⁵ Discovery of scoliosis in these children will usually "catch" it in time to employ a brace to control or prevent progression of the spinal deformity.

Recommendations for primary care physicians • The primary care physician (family practitioner or pediatrician) should carefully examine the child's back for scoliosis and kyphosis as outlined in Figures 1-3. If he feels scoliosis or kyphosis is significant, he obtains an x-ray. Scoliotic or kyphotic x-ray should be a 14 x 7 standing anteroposterior or lateral thoracolumbar spine. A standing x-ray is the one necessary to diagnose the deformity and document the amount of the curve. A supine x-ray would be inadequate. If significant scoliosis or kyphosis is detected, the child should be referred to an orthopedist either as a private patient or to local Children's Medical Services Clinic or one of the free children's hospital screening clinics such as the Florida Elks Children's Hospital at Umatilla, Nemours Children's Hospital at Jacksonville, Shriners Children's Hospital at Tampa, All Children's Hospital, St. Petersburg or Variety Children's Hospital in Miami.

Problems Encountered ● 1. Sheer Numbers of Positive Examinations: Our screening nurses are trained to detect a rib or lumbar hump and they have indeed become quite skilled and conscientious in detecting these humps, hence the large number of children presenting for examination. We have no easy and inexpensive way to separate children with minor curves from those with major curves except for examination by the physician and eventually an x-ray. However, after the first x-ray examination, a curve may be followed by observation of the size and/or angle of inclination of the hump. Bunnell from the Nemours Children's Hospital in Wilmington, Delaware has perfected a specially designed inclinometer that measures the angle of trunk rotation

represented by the hump. The method is simple, reliable and inexpensive and is easily taught to lay personnel in scoliosis screening. It shows promise of eliminating a large number of false positives.⁶

2. Failure of Parents to Follow Through with Recommendation to Report to Physician: This happens for reasons of ignorance, fear and inability to afford a private physician. In our first year of screening in Orange County, we sent a postcard home to the parents hand carried by the child. This was a mistake; many of the children never delivered the card. We solved the problem by mailing the cards.

Ignorance and fear can be countered by communication, transmitting the scoliosis information to the parent by printed material, emphasizing the possible complications and need for early care. Free scoliotic screening is offered by county health physicians, Children's Medical Services and the various children's hospitals.

Ignorance and fear can be countered by communication, transmitting the scoliosis information to the parent by printed materail, emphasizing the possible complications and need for early care.

- 3. Failure of Primary Physician to Advise the Family Properly: He may ignore the referral and dismiss the child without examination. If a rib hump is found, it may be downgraded in importance as being of little consequence.
- 4. Failure to Obtain Adequate X-Ray: The primary care physician may fail to order an x-ray or may obtain a supine film which fails to show the real amount of curve.

Table 4. — Florida Screening 1982-83, Grades 6-9,

	11 Districts, 67 Counties.
	Total
Referred.	
*Includes s referral.	ome carry-overs from last year who completed

Table 5. — Number of Students Eligible for Scoliosis Screening - 1984.



Fig. 1 - A classic rib hump seen from posterior as scoliotic patient bends forward with fingertips and palms together.



Fig. 2 — The same rib hump as Figure 1 viewed from anterior.

PROCEDURE:

Screener: Sit a few feet in front of the tape mark which was placed on the floor. Place Scoliosis Screening Report Forms on a table next to screener.

> If necessary, throughout the screening, remind the student to stand erect, neither "at attention" nor slouching. Stand with feet together, knees straight, arms held relaxed at sides.

Student: Enter

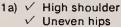
- Name on Class Roll
- 1. FACE SCREENER
 - a) Stand erect
 - b) Bend forward -Palms together
- 2. BACK TO SCREENER
 - a) Stand erect
 - b) Bend forward -Palms together











- Unequal arm to body spaces
- b) V Rib hump ✓ Uneven contour
- 2a) V High shoulder √ Curved spine
 - ✓ Uneven shoulder blades
 - ✓ Uneven hips or waist creases
 - ✓ Unequal arm to body spaces
 - b) V Rib hump
 - √ Lumbar (flank) hump
 - ✓ Uneven contour
- 3a) 1 Excessive swayback Guide: Refer if it prevents bending forward and touching ankles.
 - Excessive roundback
 - Unusual contour or hump (Normal: Smooth, rounded curve)

3. TURN LEFT SIDE TO SCREENER

- a) Stand erect
- b) Bend forward -Palms together





Fig. 3 — Procedure for school scoliosis screeners.

Reprinted with permission from "Screening for Scoliosis in Florida Schools" published by the Florida Orthopaedic Society, 1981.

- 5. Failure to Appreciate Progression of Curve on Followup: This is a common error in treating scoliosis. Either inaccurate measurements are made or comparison with previous x-rays is not done. Unfortunately the orthopedist may be as guilty as the primary care physician on this one. This may be remedied by careful comparison of successive films at four month intervals in growing children with scoliosis.
- 6. Incomplete Statistics: From the schools, we need additional information from the postcard filled out by the physician on numbers of children confirmed to have scoliosis and type of treatment begun (observation, brace, L.E.S.S.* or surgery).

From the treating physicians we need to know the etiology of the scoliosis, its curve pattern and its magnitude as well as treatment elected. Such information is difficult to obtain statewide from busy physicians. We hope to solve this with a simplified computer card form to go with each positive child.

Training films are available to those responsible for screening and/or training new screening personnel: Spinal Screening Program (Scoliosis Research Society), Scoliosis Screening for Early Detection

(Gillete Children's Hospital), and School Screening for Scoliosis (slide cassette training for screener). Contact the Florida Orthopedic Society, Scoliosis Screening Committee, Post Office Box 18564, Tampa 33679.

*Lateral Electrical Spine Stimulation

Acknowledgment

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The cost of no prenatal care

Walter J. Morales, M.D., Ph.D., Betty J. Vaughn, M.D., N. Donald Diebel, M.D., Ph.D.

No cold statistic expresses more eloquently the difference between a society of sufficiency and a society of deprivation than the infant mortality rate. K. Newman, Infant Mortality and the Health of Society

Perinatal mortality rates in the United States have experienced remarkable declines over the past 35 years, from 39.7/1000 live births in 1950 to 29.3 in 1970 to 17.7 in 1980,¹ undoubtedly a reflection of continued advances in fetal-maternal and neonatal medicine. Nevertheless, as our 17th place ranking indicates, the perinatal mortality rate in this country substantially exceeds that of other industrialized nations.²

The data indicate that although low birth weight (LBW) infants weighing less than 2,500 grams constitute less than 10% of the total neonatal population, they account for up to 75% of the perinatal mortality.³ Therefore, improved neonatal outcome can only be accomplished through a reduction in the rate of prematurity.

The results of a recent study⁴ completed at Orlando Regional Medical Center involving 488 very low birth weight (VLBW) infants are summarized in Table 1. All infants were under 1,500 grams

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and gestational age less than 33 weeks and were delivered over the four year period 1981 through 1984. The data demonstrate the remarkable inverse relationship between birth weight and neonatal mortality, length of stay in the neonatal ICU, and neonatal ICU cost. Further, the data show that indeed for gestations between 26 and 33 weeks, each day lost of intrauterine life resulted in three days of neonatal ICU care. Moreover, for each ten days of additional intrauterine life, neonatal mortality was decreased by about 50%, thus demonstrating that in spite of great technological achievements in neonatal medicine, "maternal ICU" is still in general the superior environment for the immature fetus. Therefore, once more it must be emphasized that if one is to achieve substantial reduction in the perinatal mortality rate, it is imperative that the rate of prematurity be decreased.

Creasy and associates⁵ demonstrated that the rate of prematurity could be reduced through an intensive program of patient education regarding the subtle signs of premature labor, identification of those patients at risk for prematurity and the aggressive managment of premature labor. From the efforts of this study evolved the Creasy protocol adopted by prenatal care clinics in Florida in 1983.

While the Orange County Health Department (OCHD) actively screens and evaluates each patient enrolled in its prenatal clinics for risks of premature delivery and possible referral to the High Risk Obstetrical Clinic (HROC) for more extensive monitoring, restricted funding has resulted in the exclusion of patients with a gross income exceeding poverty level: \$4,980 single patient through \$10,200 for a family of four.

Despite a 30% population growth in Orange County over the past eight years, the number of

Table 1. — Outcome of Very Low Birth Weight Infants. WEIGHT 1001-1200 1201-1500 801-1000 gm <800 gm 194 Number VLBW Babies 74 96 124 Average Gestational Age (weeks) 28 30 31 27 9(5) Mortality No(%) 49(66) 26(27) 18(15) 115 72 64 49 Average Hospital Days in NICU \$39000 \$27000 Average Cost Per Surviving Infant \$105000 \$52000 Intraventricular Hemorrhage (%) 78 66 35 25 60 48 35 Respiratory Distress Syndrome (%) 62

obstetrical patients served by the OCHD clinics has been reduced by 50% as a result of budgetary restrictions.

The purpose of this study was to quantitatively establish the cost/benefit effects of the current health care policies and to propose alternatives.

Materials and methods ● Over the two year period January 1983 through December 1984, there were 10,011 deliveries at Orlando Regional Medical Center, a tertiary care facility serving Central Florida, and of these 994 (10%) received no prenatal care. Of the 9,017 patients who received prenatal care, 6,220 (69%) were managed by private attending physicians, 2,432 (27%) were followed at the OCHD and 365 (4%) at the HROC. The outcomes of these pregnancies were studied in terms of incidence of premature births (LBW and VLBW infants), rates of stillbirth, neonatal mortality and neonatal care costs, to establish a quantitative effect of limiting prenatal care.

The data were analyzed by means of the Chisquare and the Student t-tests. Differences were considered significance at a .05 level.

Results • The race, age and parity distributions of these groups of patients are shown in Table 2. The medical complications of those patients followed at the HROC are summarized in Table 3.

Table 4 summarizes the outcome of these pregnancies. As shown, the incidence of LBW and VLBW infants was significantly higher in the group of patients with no prenatal care, 34% vs 8% and 13.5% vs 1.5% respectively, statistically significant at p < .001. Furthermore, although dealing with patients with significant medical complications predisposing to premature birth and poor pregnancy outcome, the rate of prematurity among patients receiving prenatal care at the HROC, 13% LBW and 2.7% VLBW, was considerably less than the group with no prenatal care.

Table 2. — Characteristics of Patients.						
		F	PRENATAL CARE			
	None	Private	OCHD	HROB		
Number of Patients No(%)	994(10)	6220(62)	2432(24)	365(4)		
Teenage Pregnancies No(%)	206(21)	217(3)	730(30)	55(15)		
Primigravida No(%)	278(28)	1866(30)	806(33)	88(24)		
Race						
Caucasian No(%)	606(61)	5474(88)	1265(52)	201(55)		
Noncaucasian No(%)	388(39)	746(12)	1167(48)	164(45)		

Lack of prenatal care also resulted in a substantial increase in the rates of neonatal mortality and stillbirth, 32.2 and 26.2/1000 live births respectively, when compared to those with prenatal care, 3.54 and 9.5/1000 live births, statistically significant at p < .001. Similarly, the average neonatal cost per surviving infant in the group receiving no prenatal care was \$5,080 as compared to \$760 in the patients whose mothers had received prenatal care, p < .001.

Discussion ● The results from this two year study involving 10,011 patients demonstrate that lack of prenatal care resulted in a fourfold increase in premature births and fivefold increase in perinatal mortality. Even when compared to a group of 365 patients with significant medical complications, the group without prenatal care had substantially worse pregnancy outcomes, thus indicating that, indeed, lack of prenatal care is the single most significant adverse parameter affecting pregnancy.

The results from this two year study involving 10,011 patients demonstrate that lack of prenatal care resulted in a fourfold increase in premature births and fivefold increase in perinatal mortality.

The rising cost of medicine has understandably resulted in a limitation of funds available for obstetrical and neonatal care. However, aside from the ethical and moral considerations associated with the parental grief from poor pregnancy outcomes, factors never to be minimized by health care providers, the cost-benefit consequences of the current policy of limiting prenatal care funds can be quantitatively estimated. Neonatal ICU care based on 1983 costs resulted in an expenditure of \$5,916,000 in the group of patients without prenatal care. The average cost of providing prenatal care in the OCHD clinics in 1983 and 1984 was \$550/patient. Thus, \$546,700 would have been required to provide obstetrical care to 994 "walk-in" patients who delivered at Orlando Regional Medical Center with no prenatal care. Since based on the outcomes of patients receiving prenatal care, it would have been expected that 1.3% of live born infants would have required neonatal ICU care at an average cost of \$44,150/patient; the approximate total medical cost, had prenatal care been provided to the 994 patients, would have been \$1,117,000. Thus failure to provide initial funds for prenatal care resulted in an overall net additional cost of \$4,798,000 in this one center alone.

One may also note that the difference in the average neonatal cost between the group with no prenatal care and those with was about \$4,000. Thus 854/J. FLORIDA M.A/OCTOBER 1985/Vol. 72, No. 10

Table 3. — Medical Complications of High Risk Clinic Patients.

N	lumber
Premature Labor	54
Chronic Hypertension	46
Diabetes Mellitus	66
CLASS A 22	
CLASS B 13	
CLASS C 23	
CLASS D 5	
CLASS R 3	
Pylonephritis	29
Renal Disease	13
Asthma	16
Epilepsy	19
Collagen Vascular Disease	9
Thyroid Disease	9
Cardiovascular Disease	9
Severe Anemia	8
Drug Abuser	16
Recurrent Fetal Wastage	23
Incompetent Cervix	15
Rh Immunization	5
Premature Rupture of Membranes	11
Hepatitis	4
Other	13
	-

failure to spend \$550 for maternal care resulted in \$4,000 spent in neonatal care, i.e., for each dollar not spent for prenatal care, \$7 are added to the total prenatal expenditure.

As dramatic as the cost and perinatal mortality and morbidity figures are in this two-year study at ORMC resulting from a fiscal policy which fails to provide the necessary funds for preventive care, it is reasonable to expect that these findings are representative of other obstetrical centers throughout Florida. Thus, the total yearly health bill throughout



Table 4. — Effect of Prenatal Care on Pregnancy Outcome.

DD	CA	1 4	T A 1	CA	DE
PK		JA.	IΑI	- U.A	١ĸ٢

	None	Private	OCHD	HROC
Number of Patient No(%)	994(10)	6229(62)	2432(24)	365(4)
Cesarean Section				
Cesareari Section				
Total No(%)	209(21)	1665(27)	425(17)	82(22)
Primary No(%)	111(11)	1201(19)	303(12)	55(15)
Low Birth Weight				
(LBW) < 2500 gms No(%)	339(34)*	503(8)	192(8)	49(13)
(VLBW) < 1500 gms No(%)	134(13.5)*	98(1.6)	29(1.2)	10(2.7)
Stillbirth Rate**	26.2*	8.4	11.9	13.7
Neonatal Mortality**	32.2*	3.53	2.88	8.21
Average Neonatal Cost				
for Surviving Infant	\$5080*	\$780	\$660	\$1090

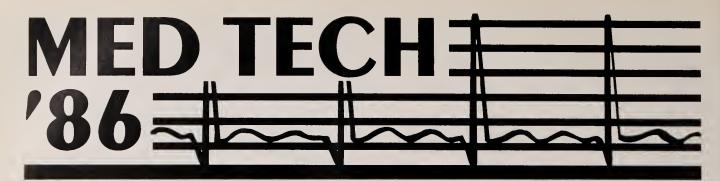
^{*}p<.001

the state must reach totally awesome proportions. It is, therefore, imperative to shift the emphasis from that of the acute care of the sick mother and neonate to the far less costly and more efficient programs of preventive medicine. This can be achieved through ensuring that all expectant mothers throughout the state are provided adequate prenatal care. Also emphasizing extensive sex and contraceptive education would help avoid the high percentage of uplanned and unwanted teenage pregnancies that contribute a high percent to premature birth and perinatal morbidity.

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^{**}Per 1000 Live Births OCHD Orange County Health Dept., HROC High Risk Obstetric Clinic





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The pecuniary benefits of medical care

Every month the medical and lay literature reminds us of the enormous expense of health care. In 1984 the cost of medical care in the United States was 387.4 billion dollars, i.e., \$1580 per person or about 10.6% of the gross national product. Physician services cost 75.4 billion dollars (19.5% of the total); dentists received an additional 25.1 billion dollars (6.5% of the total). The annual pronouncement of the health care expenditure figures automatically triggers a burst of editorial and political criticism. The medical community is being chastised for permitting the cost of health care to escalate. It is a moot point as to whether physicians, hospital administrators or medical academicians are in part or in whole responsible for the increase in cost, and I need not address this. I, however, do wish to explore the financial benefits of the increase in health care spending. Unfortunately the volume of studies examining the positive economic benefits of increased spending and health care is slender. A scan of the medical economics literature of the last three years reveals that studies on health care costs outnumber studies on financial benefits by a ratio of 98:1.

The benefits of health care to a patient and the patient's physician are usually perceived in terms of pain relief, disease cure or amelioration, alleviation of disability or prevention of more severe or fatal outcomes of illness. These outcomes are difficult to compute and, therefore, are of trivial concern to the health care fiduciary. Health economists, however, will acknowledge certain positive outcomes of health expenditure, e.g., reduction in mortality rates, savings engendered by prevention of conditions that will demand more intensive future expenditure of health care resources and prevention of wage loss.

The decline in mortality rates, particularly for white males, levelled off between 1950 and 1970. In the decade from 1940 to 1950, the mortality rate for the entire population dropped 22% but then fell less than 4% for some segments of the population per decade between 1950 and 1970. This stimulated Fuchs and a few other medical economists to express great misgivings about further expansion of health care investment. However, the introduction of Medicare and Medicaid and the increase in personal consumption of health care that began in the late 1960s and 1970s initiated a plunge in the slope of the mortality rate that has never been seen previously. The overall reduction in mortality dropped 20% in the 1970 and 1980 decades. The greatest reduction in mortality rate has occurred in the 45 to 54 and 65 to 74 year old age groups.

Mean mortality rates are listed in Table 1. As we expect, rates are lower for females than males and lower for whites than blacks. Ischemic heart disease and cerebrovascular disease account for 50 to 60 percent of all deaths.

Hadley published an extensive study on the relationship between medical care use and mortality. His study population was large and national in geographic distribution, examined both urban and rural areas and included groups of all ages, sex and race. He discovered a significant correlation between the use of medical care and the decrease in mortality. His statistics revealed that a 10% increase in medical care expenditures per capita reduced future mortality rates for the whole population by 1.6%. For some groups, such as white males who are in their prime earning years between the ages of 45 and 64, the estimated decrease in mortality was even larger at about 3%. Translating these percentages in-

Table 1. — Mean Mortality Rates; Deaths/1000 Adult Cohorts

Age	White Male	Black Male	White Female	Black Female
45-64	13.86	22.82	6.57	13.88
65+	75.81	72.30	46.09	57.30

to dollar and human figures demonstrated that each additional \$100,000 spent on medical care would prevent between 0.3 deaths in the 45 to 64 year old white female population, 1.9 deaths in the 45 to 65 year old white male population and between 3 and 3.9 deaths in the black male and female populations respectively.

A cynical economist might ask if this expenditure of an additional \$100,000 is justifiable in monetary terms alone. What he is really asking is, "What is the dollar value on life?" This is a most difficult figure to assess, but Dolan et al. attempted to quantitate this.2 Hadley reported that each additional \$100,000 spent for medical care would save 1.9 lives in the 45 to 64 year old white male group. Dolan estimated that the value of life (expressed in 1977 dollars) for a male in the 40 to 45 year old age group was about \$180,000, in the 50 to 54 year old age group \$125,000, and in the 60 to 64 year old age group \$45,000. Preserving 1.9 lives in the 40 to 65 year old age group, therefore, would justify the expenditure of an additional \$100,000 in medical care. Furthermore, Dolan's estimates — if expressed in 1985 dollars — are quite low; an average 45 year old white male in this age group now earns over \$20,000 per year and (even allowing for the discounting of the future value of money) he would be expected to earn about \$500,000 during the remainder of his lifetime. Averting the death of a man with this type of earning potential is economically sound.

Surprisingly, similar estimates of the value of increasing medical expenditures apply to infant mortality rates. A 10% increase in health care spending in this age group results in about a 1.5% reduction in the mortality rate. For every increase of \$100,000 in medical care, 1.3 black and 0.4 to 0.5 white infant deaths will be prevented. From 1960 to 1976, expenditures for infant health care increased and infant mortality fell 42% (from 26 to 15.1 deaths per 1000 live births). Thus, for both adults and infants, increased spending for health care results in fiscal payoffs which are measurable.

A second method for analyzing the pecuniary benefits of medical care is to examine the savings 858/J. FLORIDA M.A./OCTOBER 1985/Vol. 72, No. 10

engendered by appropriate and timely utilization of the health care system. For instance, perinatal care for infants born to mothers who received no prenatal care, cost society 3 to 11 times more than infants born to mothers who received adequate prenatal care.

Long-term therapy for the management of hypertension has had salutary effects on the incidence of strokes, ischemic heart disease and other cardiovascular diseases and is responsible in part for the significant decrease in cerebrovascular accidents which has been observed over the past three decades.^{3,4} The annual incidence of strokes per 100,000 population observed in Rochester, Minnesota decreased from 194 in the 1945 to 1954 decade to 103 in the period from 1975 to 1979. The largest drop occurred in the economically highly-productive 55 to 64 year old group in which the incidence fell from 370 to 170 per 100,000 population.

The cost of routine treatment of hypertension (excluding cardiovascular and cerebrovascular complications) is about 5 billion dollars annually. Is this cost effective? Definitely. The cost of caring for one stroke patient in the hospital is \$13,000 to \$19,000; post hospital institutionalization if necessary requires another \$125,000 to \$250,000 per patient for the remainder of that patient's lifetime. Assuming that an antihypertensive program prevents 100,000 strokes per year, that the average hospital costs of treating a stroke patient is \$13,000 and that the antihypertensive program keeps 30,000 patients out of institutions at an average savings of \$170,000 for the lifetime of the patient, then and effective antihypertensive program will conserve over 8 billion dollars per year in stroke prevention alone. Additionally, programs aimed at reducing hypertension have greatly reduced the deaths of cardiovascular and cerebrovascular diseases by 50%.

Typical savings in costs fostered by antihypertensive programs are obviously much greater than those mentioned here and far exceed the 5 billion dollar cost per year. Additional savings that accrue from preventing hospitalizations for heart failure and renal failure have not been incorporated into these figures. Increased health care expenditures for the timely utilization of the health care system for the treatment of hypertension, therefore, has had a great payoff in lowering future consumption of health care resources.

Other examples of resource conservation can be enlisted. For instance, the use of psychotropic drugs for mental illness ablates the need for institutionalizing most of these patients and saves about \$35,000 per year for the care of a single patient. Early aggressive therapy for the arthritic patient can prevent joint destruction in over 95% of patients, and savings derived from preventing the need for one joint replacement (which now costs about \$8,000) can provide total care for an arthritic for 15 to 25 years. We, of course, could evoke many other examples from the specialties of diabetes, infectious disease and cardiovascular disease in which early medical intervention has been demonstrated to greatly diminish future demand for health care resources.

A third way to measure cost benefits is to examine the effect of medical care on job performance and wage production, but data pertaining to this are sparse. The cost to society of work lost from respiratory disease, arthritis, trauma and neurologic disease has been well documented. Studies are not available, however, that examine the effect of health care on worker productivity. The few small studies that have been published are limited to one or a few companies and indicate that a comprehensive health care plan, consisting of a physical fitness program, antismoking campaign and ready access to medical care, does increase worker efficiency and decrease absenteeism significantly.5 Stamping a dollar value on such programs that apply to all workplaces throughout society is not possible.

We have been conscripted into a system of bottom-line medicine. Since physicians control about 70% of all health care expenditures, the insurance companies, politicians and corporations are attempting to handicap us with the burden of slenderizing the health delivery process. We should not permit the trimming functions to proceed too exuberantly. We must continually remind ourselves and others that medical care is not a financial sinkhole of indefinite dimension; rather, medicine can be a conduit to significant financial benefit for all of society. Perhaps national and state medical and specialty societies need to develop strategies to extend the measurement and reporting of the monetary benefits of health care.

Obviously not all health care provides a positive financial return. For instance, it is difficult to defend, by cost benefit principles, the care of the terminally ill patient or a great deal of elderly care, but the medical care system propagates enough monetary benefits to more than justify its humanitarian functions.

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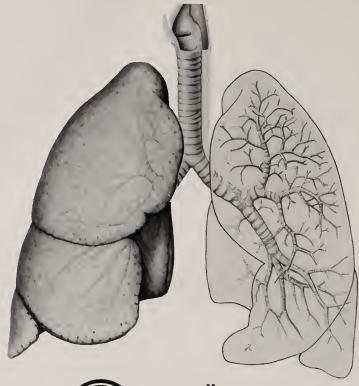


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periorime to determine susceptionity of the causative organism to Cector
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Pseudomembranous cottis has been reported with virtually appritually to drugs.
Cottis has been reported with virtually appricularly to drugs.
Cottis has been reported with virtually and some support of the color and may be consider its diagnoss in patients who develop diarrhe a in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.
Treatment with broad spectrum antibiotics afters the normal flora of the color and may perint overgrowth of clostridia Studies indicate that a four produced by Crostradium difficire is one primary cause of antibiotic associated colitis.
Mild Casses of pseudomembranous colitis usually respond to drug discontinuance alone in moderate to severe cases, manage

ment should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation when the collist does not improve after the drug has been up discontinued, or when it is severe, an

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colitis

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Coage in Unitidal — Salety and enjectiveness of this product in use in infants less than one motif of age have not been established.
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Gastrontes/final symptoms occur in about 2.5 percent of patients and include diarriera. In 1 in 70).
Symptoms of pseudomembranous collits may papear either uning or after antibotic treatment. Nausea and vomitting have been reported rately been reported fately produced to the control of the production of after tessantines and corficosteroids appear to sharing and the syndrome cases of anaphylaxis have been reported, half of which have

occurred in patients with a history of penicillin allergy (Ther effects considered related to therapy included essinophila I in 50 patients), and genital priuritus or vaginitis (less than 1 in 100 patients). Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etology, they are listed below to serve as alerting information for the physician service of the properties of the properties of the properties of the prosphatase values (1 in 40). Hemanopoetic — transient fluctuations in leukocyte count, predominantly imphocytosis occurring in infants and young children (1 in 40). Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

Note Cector* (cefactor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usuad drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic feers See prescribing information.

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FLORIDA MEDICAL

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NOTES & NEWS

1986 Leadership Conference to include House of Delegates Meeting

The 1986 Florida Medical Association Leadership Conference will be held January 24-26, at the Lincoln Hotel in Tampa. Due to change in the FMA Annual Meeting from May to September, an interim meeting of the House of Delegates will be scheduled as part of the Leadership Conference on Sunday, January 26.

The most ambitious and comprehensive program ever planned will begin with the Second Annual Leadership Skills Seminar for Women Physicians and an FMA Auxiliary meeting. Other programs scheduled Friday afternoon include a session for Hospital Medical Staffs, a meeting of county medical society executives, a workshop for Continuing Medical Education sponsors and a session on missing children co-sponsored by the FMA Auxiliary. An early bird reception will be held from 5:30 to 7:30 p.m. Friday evening.

Saturday morning offers a breakfast General Session featuring a presentation by FMA President Luis M. Perez, M.D., on present and future activities of the Association. Saturday morning will provide workshops on physician contracting, legislation and joint ventures. A General Session luncheon will follow with a prominent speaker to be announced. Saturday afternoon includes workshops on state government, unionization, risk management and media relations. To complete the day, a reception will be held beginning at 6:00 p.m.

Sunday morning hosts a FLAMPAC breakfast, and the House of Delegates will be convened at 9:30 a.m. by Guy T. Selander, M.D., Speaker of the House

Detailed information about the 1986 Leadership Conference will be mailed in October.

JCAH's board approves revised "Rehabilitation Services" chapter of 1986 AMH

At its August 1985 meeting, the Board of Commissioners of the Joint Commission on Accreditation of Hospitals (JCAH) adopted, revised and expanded "Rehabilitation Services" standards for inclusion in the 1986 Accreditation Manual for Hospitals (AMH). The standards reflect the increase in the scope and intensity of rehabilitation services provided by acute care, rehabilitation, and chronic disease hospitals. They were developed with the help of a task force of experts in rehabilitation care and were sent for field review to more than 4,700 individuals and organizations concerned with rehabilitation care.

The revised and expanded standards identify and provide quality of care guidelines for those ten rehabilitation services most commonly provided by hospitals. Those standards which are new cover prosthetic and/or orthotic services, psychological services, recreational therapy, social work services and rehabilitation medicine. Revised standards include occupational therapy, physical therapy, vocational rehabilitation, rehabilitation nursing services and speech pathology and/or audiology services. For each of these services, the standards specify relevant patient care activities and mechanisms to be used to monitor the quality of care provided.

The revised and expanded standards also provide specific requirements that programs must meet to qualify as offering "comprehensive" rehabilitation services. These requirements include providing a range of services that include medical and nursing care, physical and occupational therapy, social work, and speech and language services as well as any additional services needed by the patient population. In addition, the rehabilitation area of a hospital must have designated inpatient beds in one or more organized units with sufficient space, equipment, and qualified personnel.

The new "Rehabilitation Services" chapter will appear in the 1986 AMH, which will be published in October 1985. However, to allow facilities sufficient adaptation time, new elements of the standards will not become effective for accreditation decision purposes until July 1, 1986. Until then, the JCAH will provide recommendations pertaining to new elements in the standards. Contingencies will continue to be given, as usual, for those elements of the standards that remain unchanged.

Beginning July 1, 1986, a physician specializing in rehabilitation care will be added to the regular survey team in acute care hospitals which indicate that they have a comprehensive rehabilitation program as one of their services. This is being done to provide additional survey and educational expertise relative to the rehabilitation standards. This individual will replace the regular physician team member when surveying freestanding rehabilitation hospitals.

USF researcher's discovery helps identify infant disease

Dr. Daniel Lim is one inventor who does not expect to become rich and famous even though his product bears his name.

He considers himself a scientist — one who would rather spend his time with his test tubes and students — deriving satisfaction that he's "helped mankind."

Lim, a microbiologist at the University of South Florida College of Natural Sciences, is the developer of a culture medium to grow bacteria. Named Lim Group B Strep Broth, his medium is designed to speed up the growth of bacteria, Group B streptococci (GBS), that infect 15 to 30 percent of all premature infants. Without treatment, 50 percent of diseased infants die within 48 hours. His strep broth makes it possible to positively identify high risk mothers and babies within five hours after testing.

The bacteria that cause the disease are common and carried in the vaginal tract by 20 to 30 percent of all women, said Lim. The vast majority of these women do not have the disease. The danger is when the woman becomes pregnant and "the bacterium is transferred to the infant."

One out of every 100 infants with the bacteria will develop a serious disease. The symptoms of GBS, immediately diagnosed at birth, include respiratory infection, sepsis or blood infection and meningitis.

Lim's wonder broth, an enriched test tube culture which is the result of six months of ''looking at different enrichments, antibiotics and combinations'' and putting them together as in a recipe, was developed three years ago. It has been on the market for one year.

But Lim's research really goes back seven years when he met with representatives of Pharmacia Diagnostics, a medical research firm. Aware of his ongoing work in studying streptococci, they approached him about researching products which, he said, turned out to be instrumental in developing the GBS broth.

Lim worked with the firm in developing a kit called the Phadebact Strep B Test to identify the bacteria. Another company, GIBCO Laboratories, is packaging his broth.

Pharmacia Diagnostics and GIBCO have provided Lim with \$106,000 (\$41,000 for research and \$65,000 for chemicals, travel expenses and consulting fees) since 1978, but he does not receive any royalties, much to the surprise of his students.

"I feel the companies have been more than generous with me," Lim said. "They have supported my research here at USF. I see myself among those scientists who do not derive financial gain but derive satisfaction knowing that they have helped mankind."

Lim's testing procedure involves taking a vaginal culture from the mother just before birth and placing it in the test tube broth. Traces of the strep B bacteria will appear within five hours. Treatment with antibiotics, in most cases ampicillin, begins immediately after diagnosis.

"We can now treat infants and mothers who are high risk Group B Strep carriers and not worry about the others," said Lim. "No other technique can do this. We can avoid unnecessary treatment."

Infants, he pointed out, can have dangerous allergic reactions or other serious side effects from antibiotics. They also can build resistance to the drug so that it will be ineffective against later infection.

Lim does not take full credit for the testing procedure. He did the initial experimental lab work but when time came for a clinical evaluation of the medium, the borth went to Tampa General Hospital and, more currently, to Orlando.

A recently completed one-year study by Walter J. Morales, chief resident, obstetrics and gynecology, and Anthony F. Walsh, chief microbiologist, of the Orlando Regional Medical Center, has shown that high GBS-risk mothers treated with ampicillin six hours before birth deliver babies who are not infected by GBS.

In the test, Lim said, there were zero GBS cases in 710 mothers. In 1,274 untreated cases seven infants contracted the disease. Three died. In another 3,110 untreated patients seven GBS cases were reported with one death.

"We've made a dramatic breakthrough in eliminating death from this disease," he added.

Not content with the results, the team is researching methods to speed up the five-hour identification time, possibly developing a protocol where doctors can determine high risk mothers at bedside. They are also trying to discover more about immune systems and determine why some infants are more susceptible to GBS.

DEAN'S MESSAGE

Environmental adaptation

The evolution of the revolution is here. With the rapid growth in organizations offering alternative health care delivery systems, the future is very unclear. Insurance companies, investor-owned hospitals, non-profit hospitals, private industry, and even groups of physicians have entered the fray. At best, it is confusing to the provider and certainly must be for the consumer.

Of course, the impetus for this phenomenon is economical in nature. The retention of market share in a changing environment has become paramount. Competition and cost containment are here.

As defensive measures, some medical schools have entered the market offering health maintenance plans to their constituency.

One wonders where medical education fits into this matrix. How are students of medicine to receive a varied patient mix for their clinical education if the public is wedded to a closed alternative system? How does cost containment intertwine with education? While efficiency in patient care is an admirable goal, and cost containment can be achieved in every patient care system, will high-quality clinical instruction be permitted to continue?

A classic feature of a health maintenance organization is the front-end funding of patients with a 10% to 20% hold-back by the organization. If services provided are less than the hold-back, then there is a rebate to the physician. It is possible that personal financial gain will lead to errors in judgement regarding patient care. A two-tiered system of care will surely evolve. There may be flow charts devised and marketed for physicians to follow in order to depict the most profitable way to treat a given patient. Hence, education and the creative thought process — which have been a hallmark of our education - could be lost. A major shift in the setting of medical education would take place to a heavily outpatient-oriented setting. However, it is doubtful that the efficiency of a teaching setting will match the efficiency of a private office setting.

Therefore, the impact of the new health-care schemes on medical education must be scrutinized, and the best approach to address the problem will require the collective thoughts of all who have benefited from the high-quality medical education which we have received. Nevertheless, adaptation

to the environment is a characteristic of *Homo* sapiens. With your assistance and counsel, adaptation will occur.

William B. Deal, M.D.

Dean and Associate Vice President
University of Florida
College of Medicine

ENCORES!

An important message for all licensed physicians

The Federation of State Medical Boards is a national organization composed of state boards of medical and osteopathic medical examiners from all states, federal territories, and Canadian Provinces. At its annual meeting, held this year in Atlanta, Georgia from August 25 through 27, one of the speakers in the Saturday morning session, August 27, on fraudulent medical credentials, was Kenneth Nelson, M.D., Medical Advisor, Office of the Inspector General, Department of Health and Human Services (HHS). Dr. Nelson presented data about the Inspector General's campaign to reduce Medicare and Medicaid fraud, and to collect health care monies collected under improper or illegal circumstances.

Florida was chosen as the pilot state, and Dr. Nelson reported that HHS anticipates recovering about \$4.5 billion nationwide in funds that were improperly paid. One aspect of their efforts involves documentation of proper medical licensure by Florida physicians who receive federal health care reimbursements, and the HHS computer center in Atlanta is checking the accuracy of licensure data for all Florida physicians who now submit health care claims for Medicare and Medicaid beneficiaries. Numerous cases have already been identified and investigated of physicians who lack a current valid medical license but are submitting health insurance claims and receiving payment from the Florida intermediary, Blue Cross and Blue Shield of Jacksonville. Dr. Nelson stated that there are instances where Medicare intermediaries have not exercised enough care in reviewing the credentials of the physicians they pay federal monies to.

These investigations have already produced dramatic consequences for many Florida physicians whose only crime was the inadvertent failure to renew their state medical license as required by statute on a biennial basis. These physicians are considered to have practiced illegally during the period their license was inactive and they are ineligible to receive federal funds for services provided dur-

ing that time. Dr. Nelson related that the Inspector General will ask for a return of all money, and will also ask for interest and a penalty of \$2000 per claim.

For a busy physician with a gross annual income of \$150,000, with an estimated one third from Medicare, the result of the Inspector General's administrative action would be a payback of about \$50,000 per year, plus interest and penalties of \$2000 per claim. It is likely in a situation such as this, that a total reimbursement will be demanded of \$100,000 or more per year in which the physician practiced with an inactive license. Failure to pay these monies would result in a forfeiture of future participation in Medicare and Medicaid, and possible other legal sanctions, such as having liens placed on personal properties and other assets. If the Inspector General suspected any fraudulent motives in the physician's practice or billing for federal money, criminal charges would also be added.

Aside from these federal difficulties, these physicians face administrative legal problems in Florida for having practiced with an inactive medical license, and for having failed to renew their license in a timely fashion as proscribed by law. The Inspector General's office has been working closely with the Florida Department of Professional Regulation (DPR), and the Board of Medical Examiners in this

All licensed physicians are obligated to keep the Board of Medical Examiners notified of their proper address, and they must make certain to keep their medical license valid. All renewal registrations are issued for two years and the present renewal will expire on December 31, 1985. All physicians should receive a computerized renewal application by November 1984, but if this fails to arrive, or if the physician fails to mail the registration form back to DPR with the proper amount of money, his/her medical license will automatically become inactive on January 1, 1986. If that physician practices in 1986 with an inactive medical license, that practice is done so illegally and in violation of state law. The physician will face an administrative complaint and penalties by the Board of Medical Examiners, including an administrative fine and a reprimand. In addition, any monies received from federal, and possibly even private insurance carriers during this period when the license was inactive, must be returned to the government with interest and penalties.

Several Florida physicians have already been disciplined by the Board of Medical Examiners for having failed to renew their license, and for having practiced with an inactive license. They were issued a reprimand and an administrative fine upon the reinstatement of their license, and they face grave financial and possibly even legal sanctions from the federal government. Several physicians, including one from South Florida, had practiced for as long as three years with an inactive license and he may be asked to reimburse the federal government for several hundred thousand dollars or more. In addition, they face the possible loss of participation in Medicare and the devastating effect that could have on their practices. It is uncertain now what sanctions, if any, will be applied by private insurance companies. States attorneys could also, if they wish, file criminal charges for practicing medicine without a medical license, which is a third degree misdemeanor.

All physicians must possess a current valid medical license. Doctors should keep the wallet registration certificate in their wallet or on their person in some other way, and they should check it periodically to verify the listed name, address, and expiration date. Failure to renew, even when done inadvertently in the absence of malice, can result in severe difficulties and should be avoided by the relatively easy process of renewing in a timely fashion and notifying the Board of Medical Examiners of any address change.

Endorsement licenses • An analogous situation has arisen when physicians, who receive a Florida medical license by endorsement, fail to notify the Board of Medical Examiners of their practice, as required by statute, during the first three years in which they possess that endorsement certificate. The holder of an endorsement license must prove one year's medical practice in Florida, commencing during the 36 months after the license was issued, in order to make that endorsement license permanent and unrestricted. If the holder of the endorsement license fails to do so, that license is declared null and void on the third anniversary date of its issuance, and practice after that time is done with a license that is null and of no legal authority.

Physicians who receive an endorsement license, must notify the Board of Medical Examiners of any change of address or status, and must make certain to document their one year practice in Florida, which must have commenced before the third anniversary date of the issuance of the endorsement certificate. Extensions of the three year period are made to physicians in the military or residents at approved hospital training programs.

If there are any questions about biennial renewal, inactive license status, or Florida endorsement certificates, please contact Mrs. Dorothy Faircloth, Executive Director, Board of Medical Examiners, 130 North Monroe Street, Tallahassee, 32301.

> Richard J. Feinstein, M.D. Miami

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What kind of justice is this? Save us from the lawyers

The young professional couple had frustration in their voices, vengeance in their hearts and a lawsuit lurking in the back of their minds the first time they called. They were a columnist's dream, living symbols of a problem.

They had been stood up by a moving company, literally left on the doorstep when the moving van did not show up on what was supposed to be their last day in Washington.

He was already en route to their new home, and she was left with the kids, the dog and a 48-hour disaster. After perfunctory apologies, the movers admitted they had deliberately overbooked and come up short of vans; "we'll try have a truck there tomorrow afternoon." Of course, the people who'd bought the house were planning to move in in the morning.

Weeks later, the moving company reluctantly, begrudgingly, with not a twinge of remorse, agreed to pay their weekend motel bill plus a couple hundred bucks of other out-of-pocket expenses.

"Is that all we get?" the couple asked the other day. What about the two-day nightmare, the screaming kids, the anxiety and emotional damage? Somebody ought to make them pay, the victims argued. Otherwise what's to stop them from doing this to other people?

Shouldn't businesses that do wrong by their customers have to pay?

That question goes far beyond innocent Yuppies who lost a weekend out of their lives because of an unscrupulous moving company. It affects the women who suffered miscarriages, infections and death due to the Dalkon Shield made by A. H. Robins Co. And the people who died after taking Oraflex, the arthritis drug once made by Eli Lilly and Co.

Each of these cases provides evidence that America has no idea what to do about rogue businesses. We have no effective system for compensating the victims of business misdeeds, no good way of punishing the wrongdoers.

Look at how government regulators handled the case of Oraflex, a drug the government says has been "possibly linked" to 49 deaths in this country. Lilly admitted it did not disclose that it knew four people had died and six others had become ill after taking Oraflex. It is a violation of federal law not to report adverse reactions to a new drug; Lilly pleaded guilty.

So what did our government do? It gave Lilly a limp-wristed slap and charged the company with 25 misdemeanors, each carrying a \$1,000 fine. A \$25,000 fine for covering up facts that might have prevented 49 deaths.

If the alleged victims of Oraflex are to get justice, it will have to come in the courts, where dozens of lawsuits are now pending.

What happens to the Oraflex cases will depend not on whether the company did right or wrong, but on how the plaintiffs' lawyers do in court. If they outpoint Lilly's lawyers and persuade a jury to award punitive or compensatory damages, the attorneys may win millions for their clients or their heirs. If they screw up or are overpowered by Lilly's legal staff, their clients may not get much.

If there ae a hundred different lawsuits and a hundred different courts, there will be a hundred different verdicts. Not all of them will be just, but all of them will be justice as we know it.

Similar injustices are already occurring in the thousands of lawsuits filed over the Dalkon Shield. Robins has been fighting every claim, insisting its IUD is no more dangerous than any other. Robins has been winning some cases, but losing most of them — losing so many that last month it filed for bankruptcy court protection in hopes of minimizing its losses.

Robins' decision to duck into bankruptcy court is, by any reasonable standard of business ethics, a dirty trick. Robins is not bankrupt, not even close to it, not even after paying — with the help of its insurance company — \$378 million in Dalkon Shield damages and another \$107 million in legal fees. What Robins is trying to do is cut its losses, put a ceiling on the cost of the 5,100 Dalkon Shield claims that are still pending and avoid having its remaining assets nibbled to death, one verdict at a time.

Filing for bankruptcy is a dirty trick, but who can blame them? There is no more justice for Robins in the trial-by-tort system than there is for the women who wre killed or maimed by the Dalkon Shield. Some of them have gotten millions, others not a dime. It depends on the whim of judge and jury, the denouement of duels between courtroom gladiators.

When the legal fees in any series of cases top \$100 million, it's clear that lawyers are part of the problem. Without aggressive plaintiffs' counsel, there would be no compensation for the victims of corporate crimes. But the lawyers are largely responsible for the entire nation's befuddled view of how victims of wrongs should be compensated.

We have developed not only a legal system but also a national mindset that cannot distinguish between the trivial and the tragic when it comes to injury. Our courts cannot provide justice to either party in tragedies like the Dalkon Shield, yet we continue to insist we are entitled to punitive compensation when the moving van does not show up on time. I'm sympathetic with those folks, but the implications of their demand for recompense are more outrageous than the wrong they suffered.

No less trivializing to our court system is the lawsuit filed in Virginia recently by a woman who, while pregnant, was accused of trying to shoplift a basketball from a sporting goods store. They took her in the back room and made her prove she was not hiding the ball under her maternity top. The incident undoubtedly was not funny to her, but is a few minutes of hassle any justification for the \$500,000 claim for punitive damages she has filed?

Egged on by our legal advisers, we have come to believe that for every wrong, there is a right to compensation in the courts. But we have to begin acknowledging that lawyer-to-lawyer combat is not the only way to assess blame and determine damages. There has to be a better way.

Jerry Knight

Reprinted with permission from *The Washington Post National Weekly Edition*, September 9, 1985.

Fee splitting in the '80s?

Almost exactly 20 years ago I began practicing Pathology in Lexington, Kentucky. The first order of business was to get my license registered at the courthouse. I had had my Alabama license registered when I was a resident and I imagined that it would be the same. You take your license down there and pay a couple of bucks and the lady stamps some stamps and so forth and it is done. Not so in Fayette County, Kentucky. In addition to all of the above you had to sign "The Book."

The Book was a large leather bound tome about eight inches thick composed of blank pages upon which had signed all of my predecessors all the way back, I suppose, to Ephraim McDowell, assuming the county included Danville back in pioneer days. In signing The Book, however, I had sworn that I was neither an "advertising doctor nor itinerant surgeon."

It is inevitable that things would change from pioneer days or even from the 60's. I do not know if physicians still have to swear and sign but I do know that the FTC has said that an organization in the learned professions (like the AMA) cannot tell its members NOT to advertise. I am happy to see that physicians have not indulged in the TV excesses and

poor taste that the attorneys have. As for itineracy, I would imagine that any surgeon who works at UCH, Town 'n Country, and Brandon travels more in a day than could have been dreamed of back in those days.

Another item of ethical concern involves fee splitting. In times past I feel that we knew what fee splitting was. The AMA Current Opinions of the Judicial Council for 1984 says, "Payment by one physician to another solely for the referral of a patient is fee splitting and is improper both for the physician making the payment and the physician receiving the payment." It states further, "In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the physician on matters of referral. All referrals and prescriptions must be based on the skill and quality of the physician to whom the patient has been referred or the quality and efficacy of the drug or product prescribed."

This seems to be pretty clear and I feel that we all have an awareness of what is meant. Now comes the 80's with prepaid plans and a multitude of different arrangements with physicians. In some of the plans a physician (or clinic) is paid a total amount of money for each patient (capitation) from which the physician must provide all health care including the services of consultants. It is easy to see that this physician will have more of this total amount left (dare I say "profit") if he (1) has fortuitously healthy patients or (2) under utilizes consultants or (3) chooses consultants on the basis of negotiations for fee discounts.

The last two approaches could lead to compromise of patient care and the latter has the same net effect as fee splitting. The consultant gives part of his fee to the referring physician in return for the referral — that it is given before or after the fact does not lessen the effect. It could be said that it is done because of the risk-taking of the referring physician. It could be said that these arrangements are those of the plan and the physician is just going along with them. Remember that the plan managers and administrators are businessmen and that physicians are supposed to be professionals.

It is said that physicians must become better businessmen in their practices. I agree that we should be more efficient, more prudent, and better utilizers, but I do not agree that medicine is no longer a profession in which fee splitting in any form can be condoned.

Glenn S. Hooper, M.D. Tampa

Reprinted with permission from the Hillsborough County Medical Association Bulletin, September 1985, Vol. 31, No. 4.

Health policy in 1985 and beyond

Editor's Note: This is the prepared text of William L. Roper, M.D.'s Jerome Cochran lecture, which was to have been given at the annual session of the Medical Association of the State of Alabama on April 19, 1985. Dr. Roper, an Alabama physician, was forced to cancel his appearance due to the death of his mother.

I am grateful to the Medical Association of the State of Alabama and especially to Dr. Hyman for the invitation to speak to the Annual Meeting.

The year 1985 is a challenging one for American medicine. Although it is almost a cliche, it bears repeating that we are in the middle of a fundamental revolution of the American health care system.

Someone else recently put it another way by saying "The revolution is on. It may not have reached your area yet, but if you haven't heard the shouting you are not listening."

I was asked to give the Federal government view of health policy and I welcome that opportunity. It is important to put all of this in context. In recent weeks much of the attention of Washington and the rest of the country has been focused on the Federal government budget for next year. The President's proposal for Fiscal Year 1986 calls for more than 50 billion dollars in savings from what would otherwise be spent. As is rightly the case, health programs are included in these spending reduction proposals. The fundamental policy decision about this budget is "freeze." In an almost across the board fashion, an effort is being made to hold the line on spending in Fiscal Year 86 at the level it is in Fiscal Year 85. Much more will happen on the budget later this year and I am certain that all of you will be interested in specific items such as the proposal to exclude the physician fee freeze under Medicare for another twelve months.

But there is life beyond the 1986 budget. Despite all of the discussions now and in the future about budget matters, we need to continue to focus on the kind of health care system we want to shape for the future. We in America have the finest health care system in the world today. More of our citizens receive better health care services than is the case anywhere else. But that system does have problems and we need to address those problems directly. However, it is important to point out, as the President continually does, that those problems need to be solved in a way that builds on the fundamental strengths of our health care system, not such radical change as to destroy those strengths.

During the past year I have served as Chairman of a White House Working Group on Health Policy and Economics. This group includes representatives

of the White House, the Treasury, the Department of Defense, the Department of Health and Human Services, the Office of Management and Budget, the Council of Economic Advisors, the Office of Science and Technology Policy, and the Veterans Administration. We have undertaken a fundamental review of health policy issues and are making recommendations for the President's second term agenda in health matters This review of health policy issues has presented an opportunity to look carefully at basic issues in health policy in America. I would like to discuss three of those in my remarks.

The overarching issue in health care today continues to be the cost of health care. You are probably quite familiar with the numbers — but we are devoting about 10.5 percent of our gross national product, more than 1 billion dollars per day, to health care. It is hard to turn on a television or radio or read a newspaper or magazine without being confronted with the health care cost issue. Indeed it is hard to say the words "health care" without following them with "costs." The three words are used together so often these days.

In the middle of all this media attention on health care costs, today's message is changing. In the past, all discussions about health care costs focused on what a terrible problem it was and how it was apparently beyond any sort of solution. Today's new coverage, however, presents a different story, one that is much more encouraging. The recent stories talk about what is being done to control health care spending increases, what is being done by business and industry, by doctors and hospitals, by state, local and federal governments. The rate of increase in health costs has fallen dramatically, to being only slightly more than the general inflation rate.

The Reagan Administration's position has been and continues to be that the fundamental problem that has led to such rapid increases in spending in health care is that incentives in the system have been backwards. Incentives — to patients, to families, doctors and hospitals, to the payors for health care services — the incentives have all been in the direction of increasing spending and almost no incentives in the direction of restraining spending.

There continue to be a number of myths that abound in the health care cost debate:

• One myth is that inflation is the problem. When we look carefully, it is not inflation and certainly not health-specific inflation that has led to such rapid increases in health care spending. Rather it is increases in the intensity and sophistication of the services that are provided. In other words, we are doing more and doing it better. After all, that is what has given us this world class health care system.

- Another myth is that evil providers, such as greedy doctors or rip-off hospitals, have created this problem. Obviously you know that this is not the truth. We all have wanted this top quality system; we are now coming to understand how expensive it is.
- Another myth is that if anything is changed in the health care system, quality will immediately suffer. Quality is extremely important, and you and we need to do everything within our power to insure that quality continues. However, quality should not be used as simply an argument to maintain the status quo. If the Japanese have taught us anything in their manufacturing experience, it is that quality and productivity go hand-in-hand. You can increase productivity, increase efficiency, and at the same time increase quality. Many of you are demonstrating this in your practices today.
- Another myth is that it would be easy to control health care spending if only we had the will to do so. We need to be truthful with the American people on this score. The health care industry is a major employer. If we were to cut large amounts of health care spending, institutions would close, people would lose their jobs. In addition, we need to be truthful and explain that a large amount of the spending in the health care system is for people who are near the last days of their life. Productivity gains are important, but there are ethical issues to face as well. We are having a debate as a nation on these sorts of questions, and I think we are headed toward some solutions. But we need to be clear that this Administration is quite opposed to government being the arbiter as to who can have what kind of health care services.
- A final myth is that consumers of health care services are powerless to influence the system. The picture is often painted of powerless patients who cower at the feet of soverign physicians. Perhaps that was the case some years ago, but it is certainly not the case now. Patients and families are demanding more information on which they can make decisions about their health care.

To borrow a phrase from Ben Wattenburg, the good news is that the bad news is not true. The bad news about run away health care spending is wrong, because health care professionals and others all across the country are working to make our health care system more cost efficient while focusing on quality.

The second fundamental health policy issue is a continuing debate over appropriate strategy for controlling health care costs. For ease of discussion, it is a debate between competition and regulation. This Administration is convinced that the better way to have increased cost efficiency in our health care system is through greater competition, not through increased government regulation. We feel that we have had entirely too much government intrusion in the health care system in the past.

Here again, I would point to a changing message from the news media on this issue. Only a few years ago news stories about competition in the health care industry said we cannot have competition in health care. They said that health care was different, that it was not possible to have true market forces in health care. Now, however, the debate in the news media is over whether we like the competition that we now have. As you well know there is greatly enhanced competition out there, but I would point you to the news coverage of the recent artificial heart transplants by Dr. DeVries in Louisville at Humana, as symptomatic of the news media's debate over whether competition is a "good" thing.

Whether we like it or not, and I like it, I am convinced we are going to have much more competition in health care. This comes about not because of what government has done or will do, but because of the driving engine for change in health care is the private sector, business and industry. We have come a long way in the last four years under President Reagan towards a much more competitive health care system. The prospective payment system is an important step in that evolution.

But we must be truthful, and say that the prospective payment system is not a truly competitive, market place solution to the health care cost problem. It is a nationally administered price system that has too much government involvement in Medicare operations.

I believe that his Administration should view the prospective payment system as an important step away from cost reimbursement, but that we need to move even further toward a truly competitive system. I believe that one of the things that should be considered is capitation. Under capitation, Medicare beneficiaries would be able to enroll in a variety of competitive health care plans, and government would make payments to those plans on their behalf. Rather than trying to further constrain the system by adding physician services or skilled nursing facilities to the prospective payment system, under capitation the incentives would be given to doctors an hospitals for them to make cost-effective decisions about the most appropriate way to treat patients over the long term.

Despite our having moved substantially along the road toward competition, there will be some effort toward greater government regulation of health care:

- Many members of Congress continue to push for government regulation. This comes about because they have a fundamentally different view of government's role in society than does this Administration.
- The long term solvency of the Medicare program, while improved, is a concern. If Medicare's financial condition should worsen, I believe we would see many people urging that the system be regulated in order to preserve Medicare.
- Under competition, the issue of indigent care is a much more prominent one. Competition is forcing prices down, with less possibility of cross-subsidization from one group of patients to another. A debate is underway on how society should deal with the indigent care issue. It is important that this issue be resolved so that the health care system can move toward more competition. Many people have urged that the federal government step in to solve the indigent care problem. But in the time of very high federal budget deficits, it is certainly not possible. Many states are looking to regulatory means of solving the indigent care problem. Just as we have opposed regulation at the federal level in health care we would urge states not to consider regulatory means of solving the problems at that level.
- Another push we are beginning to see toward regulation fo the health care system comes from providers. Many people in the airline industry are looking nostalgically back to the days when the Civil Aeronautics Board regulated their industry. Similarly, some doctors and some hospitals are feeling the stress of competition and are beginning to suggest that we should go back to more regulation rather than more competition in health care in order to preserve their status quo.

The third fundamental health policy issue that we confront is the future of the Medicare program. The President has repeatedly said that Medicare is at the bedrock of the nation's commitment to the elderly and disabled and that we need to strengthen and preserve it.

The prospective payment system for hospitals under Medicare is the most significant change since the inception of the program twenty years ago. The recent Trustees' report tells us that under intermediate assumptions of Hospital Insurance Trust

Fund will be solvent until 1998. This gives us time to study and evaluate alternatives for ensuring that the program will be fiscally sound long into the future. As I have mentioned, one of the approaches that seems particularly fruitful is capitation. Capitation is not an idea that only a few of us idealogues are pushing. A recent policy statement of the Chamber of Commerce of the United States urged that Medicare go to a capitated arrangement, which they described as "a defined and portable federal contribution" on behalf of each beneficiary. A recent article in *Fortune* magazine said "Vouchers. . . are the best long-term prescription for the rise in health bills." Vouchers, of course, are another way of describing capitation.

But capitation is a long term solution to the Medicare solvency question. In the meantime, there are a number of short term Medicare issues and questions. It is important that these shorter term issues be discussed with a view toward where they are taking us with the Medicare program. The following are some of these questions:

- Capital. The Administration is required to submit a report to the Congress on how Medicare's payment for capital should be handled under the prospective payment system. The Administration would like to establish a capital payment program that insures prospectivity and cost reimbursement. We feel that this would give hospital management the discretion to make such decisions. Some of these will be wise and some of them will be unwise decisions.
- Medical Education. In Fiscal Year 1986 budget, we have proposed a freeze on the direct medical education payment and halving of the indirect medical education add-on for Medicare. This has stimulated a great deal of discussion about the training of future physicians and other health professionals, and rightly so. In the time of excess numbers of physicians, and high federal deficits, it is difficult to continue an open-ended federal subsidy for the training of persons for careers that are generally very well paying.
- Physician Payment. This summer, the Administration will report to the Congress on the advisability and feasibility of paying for inpatient physician services using a diagnosis related group methodology. I know that this issue has stimulated a great deal of discussion and concern among physicians. We are in general agreement that the usual, customary and reasonable methodology no longer makes good sense. There is not agreement on how we should go in the

future. I have heard from many physicians about their opposition to "physician-DRGs." As you can tell from my remarks, I am interested in moving us more toward capitation, and I feel physician DRGs would tend to take us away from that goal.

• Professional liability. An issue of great importance to the physician community is the growing cost of professional liability. Hardly a day goes by that I am not asked what the Federal government is going to do to solve the medical malpractice problem. The AMA has a task force that has been studying the professional liability question and I am anxious to discuss further with the physician community the proposal that they will put forward.

As I said in the beginning, we are in a time of fundamental change in the health care system. The issue is not whether there will be a revolution, but whether it will be a good or bad one. The challenge that I put before you as physicians is to do all in your power to ensure that it will be a good revolution. This will be difficult, because we as physicians are no longer in the driver's seat; control has shifted from physicians to the purchasers of health care services.

What you as physicians need to do in this crucial time is to teach your patients, your purchasers if you will, to buy right. If they buy right, they will focus on efficient providers of quality health care services. If they do not, they will focus on cheap, shoddy providers. The only real alternative to teaching purchasers to buy right is government regulation. For all the reasons I have outlined above, the Administration is opposed to that as an alternative. Beyond being simply opposed, we are convinced that government regulation will not work.

What you as providers of health care services should do is work to define what quality health care means. It is no longer sufficient to say "I know it when I see it." Together we should develop quantitative ways of measuring quality so that these techniques can be used to assist purchasers in buying better services.

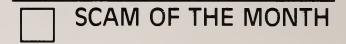
Additionally I would encourage good physicians to do everything they can to take charge of the new provider and paymnent arrangements that are being put together. I say do that now, while you still have leverage. If you do not and the health care system revolution continues without you, the good

physicians will be the last to know. However, fundamental change is underway and I think good physicians must be at the forefront of leading that change.

Finally, I would urge that you remain fundamentally committed to delivering good health care services to your patients. Despite all of this discussion of cost efficiency and economics, the basic principle is delivering quality health care services to help patients. Please do not ever forget that.

William L. Roper, M.D.

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Editor's Note: The "Scam of the Month" project was undertaken by the Missouri Task Force on Misuse, Abuse and Diversion of Prescription Drugs as part of an effort to improve professional and law enforcement awareness of some of the tricks used by abusers and others to divert prescription drugs to street and other inappropriate use. While the vignettes in this series actually occurred in Missouri, they could occur in Florida and may well have already. We convey our thanks to the Missouri Task Force for sharing this series with us.

"The girlfriend in the office scam"

Prescribers need to be alert to a frequently employed indirect professional patient scam. In such instances, a drug abuser/dealer will cultivate a social relationship with a member of the office staff (receptionist, secretary, nurse, assistant, etc.) in order to gain access to prescription pads, drugs, forged signatures or even telephone prescriptions. Such techniques are possible when office personnel are minimally supervised. In such arrangements, the professional patient has a built-in bonus. The office accomplice is frequently able to intercept calls from pharmacists attempting to verify questionable prescriptions.

Caution ● Prescribers can minimize the possibility of unethical/dishonest staff behaviors by maintaining good office discipline, tightly controlling prescription pads, communicating directly with dispensers, and being sensitive to the demands of the "street market."

in medicine, ineffective bookkeeping can try one's patients.

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BOOK REVIEWS

Book Review Editor — F. Norman Vickers, M.D.

Imaging Anatomy of the Head and Spine

By H. N. Schnitzlein, Ph.D. and F. Reed Murtagh, M.D., 334 pages. Urban & Schwarzenberg.

In the introduction the authors comented that they had desired "to present, between one set of covers, the anatomical information needed to interpret most neurologically oriented studies performed with the major imaging modalities of C.T. or MRI" and indeed this is the case. This atlas is extremely well illustrated. The quality of printing and reproduction is superb. The figures are well chosen from good original images of first class quality CT scans, cadaver specimens, and good MRI scans.

With the present use of CT and the newer modality of MRI, sectional anatomy has become increasingly important. The authors correlate well the cadaver anatomy of the head and spine in commonly used formats with the comparable anatomy of CT and MRI scans.

These images are arranged together for easy accessibility and easy comparison. In addition, radiographs are included demonstrating the planes of sections as well as a summarized description accompanying the photographs of the CT and MRI images. Basically *Imaging Anatomy of the Head and Spine* represents a photographic color atlas of gross and microscopic anatomy as well as MRI and CT anatomy in axial, coronal, and sagittal planes.

The book is easy to use and one of the best features is that photographs of the gross anatomy, CT and MRI are well correlated and presented together. The anatomical sketches are labeled well and the descriptive summaries are concise and frequently emphasize pertinent anatomical features or clinical relevant signs and symptoms.

I would recommend this atlas for all practicing radiologists, radiology residents, neurologists and neurosurgeons who are involved in daily scanning. This book should be part of the radiology department that utilizes computed tomography or magnetic resonance imaging.

Charles D. Williams, M.D. Tallahassee

 Dr. Williams is in private practice in Radiology and is Chairman of Radiology at Tallahassee Memorial Regional Medical Center and Chairman-Elect of the medical staff.

The Palm Beach Long Life Diet

By E. Joan Barice, M.D., with Kathleen Jonah, 278 pages. Price \$14.95. Simon and Schuster.

In a time when almost any nonsense about diet and nutrition finds a large following if it appears in print, *The Palm Beach Long Life Diet* offers some sensible advice and deserves a wide readership. The author, Dr. Joan Barice, is board certified in Internal Medicine and Preventive Medicine and is a former

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Assistant Director of the Palm Beach County Health Department. Drawing on her experience and interest in nutrition, Dr. Barice imparts a wealth of information on weight loss, vitamins and minerals, disease prevention, and exercise while debunking many of the myths on which the usual fad diets are based. The information is presented in a very positive, upbeat manner, however, and avoids sounding too much like either a medical text-book or the rantings that we "establishment" doctors too often resort to when asked about health and food.

Included in the text are complete menus for chemically and metabolically balanced weight loss diets for a standard or "core" week, an "easy" week, and a week of gourmet meals. Having tried some of these menus, I can attest that they are not only tasty and satisfying but bring the desired results. In a week of the core diet, both my wife and I shed the expected two pounds and felt good in the process. By adhering to the rigid schedule, we also developed a feel for the basic techniques of cooking and eating a low salt, low fat, no added sugar diet.

The use of spices and complex carbohydrate foods to increase flavor and satisfaction is especially pleasing to the palate.

The Palm Beach diet is aimed at those who are above the age of 50,though most of what it says is true for any age adult. It is recommended reading not only for patients who might ask their physician's advice about dieting, but also for those physicians who are beginning to show signs of "Dunlop's Syndrome" (i.e. done lopped out over their belts).

Henry L. Harrell Jr., M.D. Ocala

• Dr. Harrell practices internal medicine and is an Associate Editor of *The Journal*, Ocala.



See next page for brief summary of prescribing information.

Brief Summary of Prescribing Information NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.** Before prescribing, please see full prescribing information. A Brief Summary follows DESCRIPTION

Norlestrin Products are progestogen-estrogen combinations INDICATIONS AND USAGE

INDICATIONS AND USAGE

Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0 05 per 100 woman-years; in clinical trials with Norlestrin 2 5/50 involving 96,388 cycles, there was a pregnancy rate of 0 02 per 1000 woman-years

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance

CONTRAINDICATIONS

1 Thromboephlebits or thromboembolic disorders.

- NTRAINDICATIONS
 Thrombophlebitis or thromboembolic disorders
 A past history of deep-vein thrombophlebitis or thromboembolic disorders
 Cerebral vascular or coronary artery disease
 Known or suspected carcinoma of the breast

- 5. Known or suspected estrogen-dependent neoplasia
 6. Undragnosed abnormal genital bleedring
 7. Known or suspected pregnancy (See WARNING No. 5)
 8. Benign or malignant liver tumor which developed during the use of oral contraceptives. or other estrogen-containing products

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age.

Women who use oral contraceptives should be strongly advised not to smoke. The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbla ider disease, and hypertension Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

Thromboembolic Disorders and Other Vascular Problems. An increased risk of thromboembolic and thrombolic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous.

1. Thromboembolic Disorders and Other Vascular Problems. An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater in disposition. The proposition of the

continued immediately

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or

weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. Ocular Lesions. Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision, onset of proptosis or diplopia, papilledema, or retinal vascular lesions.

3. Carcinoma. Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver. In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives. Studies found no evidence of increase in breast cancer in women taking oral contraceptives, however, an excess risk in users with documented benign breast disease was reported. There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiag-nosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal manimograms, should be

or who have breast nodules, fibrocystic disease, or abnormal manimograms, should be monitored with particular care.
4 Hepatro Tumors. Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock. A few cases of hepaticcellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time 5. Usage in or Immediately Preceding Pregnancy, Birth Defects in Offspring, and Malignancy in Female Offspring. During early pregnancy female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy. There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

contraceptives

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the sched-

ule, the possibility of pregnancy should be considered at the time of the first missed period, and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed. Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attemptining to conceive. Administration of progestogen-only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy. 6 Galibadder Disease. Studies report an increased risk of surgically confirmed galibladder disease in users of oral contraceptives. 7 Carbohydrate and Lipid Metabolic Effects. Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabelic and diabelic patients should be carefully observed while receiving oral contraceptives. An increase in triglycerides and total phospholipids has been observed. 8 Elevated Blood Pressure. An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9 Headache Onset or exacerbation of migrame or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of oral contraceptives

contraceptives

10. Bleeding Irregularities. Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy. Women with a past history of oligomenorrhea or secondary amenorrhea, or young women without regular cycles should be advised that they may have a lendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. Ectopic Pregnancy. Ectopic as well as intrauterine pregnancy may occur in contraceptives.

tive failures

12 Breast-Feeding Oral contraceptives may interfere with factation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of moth-

s receiving these drugs

ers receiving these drugs

PRECAUTIONS

1 A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.

2 Preexisting uterine leiornyomata may increase in size.

3 Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.

4. Oral contraceptives may cause flittle refention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.

5 Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of raundice. If jaundice develops, the medication should be discontinued of Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.

7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.

8. Serum folate levels may be depressed.

9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.

10. Certain endocrine and liver function tests and blood components may be affected.

(a) Increased sulfobromophthalein retention. (b) Increased prothoromon and factors VII.

(a) Increased sullobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X, decreased antithrombin 3, increased norepinephrine-induced platelet aggregability (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid-binding soloutin (TBG) leading to increased circulating total thyroid-binding soloutin (TBG) leading to increased circulating total thyroid-binding soloutin (TBG) leading to increased circulating total thyroid-binding solouting (TBG) leading to increase discussions and the solouting solouting the solouting solouting solouting the solouting solou

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampiciflin.

have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS

An increased risk of the following serious adverse reactions has been associated with oral contraceptives thrombophlebitis, pulmonary embolism, coronary thrombosis, cerebral thrombosis, cerebral thrombosis, cerebral hemorrhage, hypertension, gallbladder disease, benign hepatomas, congenital anomalies

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed, mesenteric thrombosis, neuro-ocular lesions, eg. retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally gastrointestinal symptoms, breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea amenorrhea during and after treatment, temporary infertility after discontinuance of treatment; edema, chloasma or melasma, breast changes, change in weight, change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum, cholestatic jaundice, migraine, increase in size of uterine leiomyomata, rash (allergic), mental depression, reducad tolerance to carbohydrates, vaginal candidiasis, change in corrieal curvature, infolerance to contact lenses. The following adverse reactions have been reported and the association has been neither confirmed nor refuted premenstrual-like syndrome; cataracts; changes in libido, chorea, changes in appetite, cystitis-like syndrome; cataracts; changes in libido, chorea, changes in appetite as the syndrome; cataracts; changes in libido, chorea, change

Special Notes on Administration

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth
day after discontinuing medication
After several months on frealment, bleeding may be reduced to a point of virtual absence,
reduced flow may be a result of medication and not indicative of pregnancy
HOW SUPPLIED

reduced flow may be a result of medication and not indicative of pregnancy NOW SUPPLIED

Norlestrin [21] 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of live refills

Norlestrin [21] 2 5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [28] 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP Available in packages of five refills.

Norlestrin [28] 1/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 7.5 mg of ferrous fumarate, USP Available in packages of five compacts and packages of five refills.

Norlestrin [28] 1/50 is available in compacts each containing 21 pillow tablets and 7 white inert tablets. Each pillow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five refills. 0901G131

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Low incidence of side effects

CARDIZEM® (diltiazem HCl) produces an incidence of adverse reactions not greater than that reported with placebo therapy, thus contributing to the patient's sense of well-being.

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

References:

- 1 Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
- Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exerciseinducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

Reduces angina attack frequency* 42% to 46% decrease reported in

42% to 46% decrease reported i multicenter study.1

Increases exercise tolerance*

In Bruce exercise test, control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes (P<.005).

CARDIZEM

(diltiazem HCl)

THE BALANCED
CALCIUM CHANNEL BLOCKER

PROFESSIONAL USE INFORMATION



DESCRIPTION

CARDIZEM* (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy)-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+)-cis-. The chemical structure is:

Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450-98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed

to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been

Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced cor-onary artery spasm are inhibited by CARDIZEM.
 Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise.

and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH

interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked In man, dititazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of dilitazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by dilitazem.

un utilizatem ainu deraulockers. Nesting near rate is usually unchanged or slightly reduced by diffuszem.

Intravenous diffuszem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block Diffusions processed representations of the Ministerial Processes of the second of the processes of the process AV block. Dittiazem-associated prolongation of the All interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, dilitiazem slignificantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240

cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Dilitiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicytic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl dilitazem is also present in the plasma at levels of 10% to 20% of the parent drug administration is opportionally vasodilator as dilitiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of dilitiazem.

INDICATIONS AND USAGE

1. Angina Pectoris Due to Coronary Artery Spasm. CARDIZEM

is indicated in the treatment of angina pectoris due to coronary is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (testing angina with ST-segment elevation occurring during attacks).

Chronic Stable Angina (Classic Effort-Associated Angina).

CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina recognizer preprincipal programs.

reducing angina frequency and increasing exercise tolerance.
There are no controlled studies of the effectiveness of the concomiant use of ditiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

VARNINGS

1. Cardiac Conduction. CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.

2. Congestive Heart Failure. Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative

studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.

Hypotension. Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.

Acute Hepatic Injury. In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metab-General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subcautie and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

WARNINGS).
Controlled and uncontrolled domestic studies suggest that concontinuous ain uncontrolled ownestic studies suggest that com-comitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, dilitazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in invitre to bacterial tests. No intrinsic effect on fertility was observed

In rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/ky basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the burnar dose or gracial conditions.

There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk. Because many drugs are excreted in human milk was exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been

excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationshin to CARDIZEM has not been established. The most common occurrences, and their forecast their response to their forecast their served and t as well as their frequency of presentation, are: edema (2.4%),

headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence

Cardiovascular

Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure,

Nervous System: Gastrointestinal:

bid, parphatrons, congestive heart failure, syncope.
Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT,

SGPT, and LDH.
Pruritus, petechiae, urticaria, photosensitivity. Dermatologic: Polyuria, nocturia.

The following additional experiences have been noted: A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infre-quently in patients receiving CARDIZEM: erythema multiforme; leu-kopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia

Hypotension

Administer atropine (0.60 to 1.0 mg). If there

High-Degree AV Block

Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.

Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.

Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.

Cardiac Failure

Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating

clinical situation and the pugment and experience of the treating physician.

The oral/LD_{so}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{so}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{so} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity. with toxicity

DOSAGE AND ADMINISTRATION

DOSAGE AND ADMINISTRATION

Exertional Anglina Pectoris Due to Atherosclerotic Coronary Artery Disease or Anglina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be

ing dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. Sublingual NTG may be taken as required to abort acute anginal attacks during CARDIZEM therapy.

2. Prophylactic Nitrate Therapy — CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

3. Beta-blockers. (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other tablet is engraved with MARION on one side and 1772 on the other lssued 4/1/84

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Auxiliary Liaison Editor — Mrs. Walter (Isabella) Laude

Encouraging older adults to enjoy life

To enjoy life, one needs a variety of resources and opportunities. One also must be able to get help when it is needed. In order to help meet these needs in Palm Beach County, the Palm Beach County Medical Society Auxiliary combined forces with another agency to produce one of the most comprehensive guides ever seen for helping older adults to enjoy life.

This unique directory is entitled *Enjoying Life* in Favorite Ways and lists one hundred and twenty-six sources of information, opportunities, and services. Most of the listings were compiled by Laura Huntington, Chairman, and Auxiliary members Nancy Alley, Lisette Mergen, Carol Van Eldik, and Jane Wilson. They worked closely with the Sylvester Institute on Aging staff and the College of Boca



"Enjoying Life in Favorite Ways" Directory Team: (left to right) Lisette Mergen, Laura Huntington, Carol Van Eldik and Nancy Alley. Missing: Jane Wilson.

Raton, researching agencies in Palm Beach County which provide opportunities and services for senior adults to lead happy and healthy lifestyles. Research associate of the institute, Helena Toner served as editor of the directory.

The purpose of the directory is "to encourage older adults to be active and independent." It focuses on preventive health, rather than sickness, and fulfills the wish of the Auxiliary to provide ways for senior citizens to stay well and remain active.

The forty page guide is easy to read, attractively illustrated, and abounds with health tips and information which will prove extremely valuable and enjoyable for older adults in Palm Beach County, and as an example of what an Auxiliary can do to help improve the quality of life for all.

To obtain a copy of *Enjoying Life in Favorite Ways* send a check for \$2.50 payable to the College of Boca Raton, Sylvester Institute on Aging, 3601 North Military Trail, Boca Raton 33431.

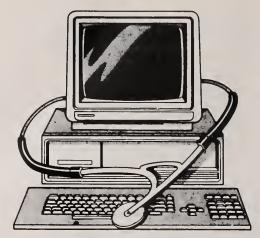
Topics covered include: "things we like to do, places for friendship, staying healthy, safety at home and on the road, information, administrative, and regulatory agencies, services for the disabled, and in times of need."

Mrs. Carol Van Eldik Council on Aging Committee Palm Beach County Medical Society Auxiliary Atlantis

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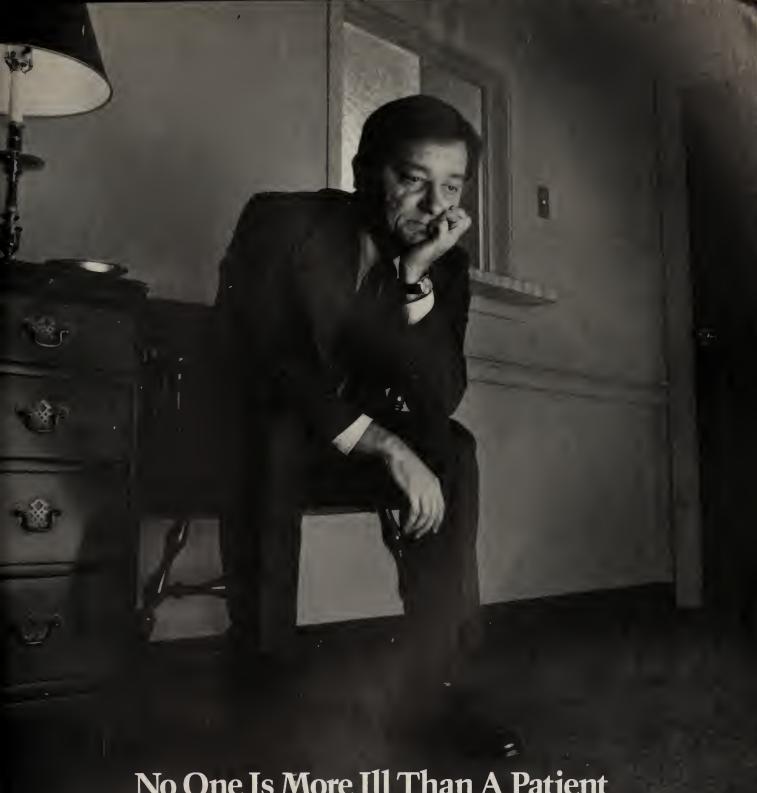
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Meetings

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NOVEMBER

Twenty-sixth Workshop in Electrocardiography, Nov. 1-4, Sheraton Sand Key Hotel, Clearwater. For information: Henry Marriott, M.D., 601 12th Street N., St. Petersburg 33705, (813) 894-0790.

Advanced Cardiac Life Support, Nov. 2-3, USF College of Medicine, Tampa. For more information: J. Paul Michlin, M.D., 12901 N. 30th St., Tampa, Fl. 33612, (813) 251-6911.

Spinal Deformities, November 3-6, Sheraton Bal Harbour, Bal Harbour. For information: Barry Silverman, 2050 N.E. 163rd Street, N. Miami Beach 33162, (305) 944-4746.

Current Advances in Perinatology, Nov. 3-9, Virgin Islands. Contact: Charles R. Bauer, M.D., Division of Pediatrics, P.O. Box 016960, Miami, Fl. 33101, (305) 547-5808.

Third Annual Meeting Florida Medical Professional Group, Nov. 8-10, Tradewinds Hotel, St. Petersburg. Contact: Walter W. Hamilton, 1201 5th Avenue North #505, St. Petersburg, FL (813) 821-9760.

Eleventh Annual Review Courses in OB/GYN, Nov. 13, Miami. Contact: Patty Mundy, P.O. Box 016960, Miami, Fl. 33101, (305) 549-6944.

Third Annual Childrens Hospital Foundation — Care of the Sick Child, Nov. 14-16, Palace Hotel, Lake Buena Vista. Contact: Joseph Chiaro, M.D., 1414 S. Kuhl Ave. Orlando, Fl. 32806, (305) 841-5143.

Eleventh Annual OB/GYN Reveiw Courses, Nov. 14-25, Sheraton Royal Biscayne Hotel, Key Biscayne. Contact: Patti Mundy, P.O. Box 016960, Miami, Fl. 33101, (305) 549-6944.

Ninth Annual Seminar: Evolution in the Total Care of the Pediatric Hematology/Oncology Patient, November 21-23, Hyatt Orlando, Orlando. For information: Cindi Butson, P.O. Box 13372, University Station, Gainesville 32604, 904-375-6848.

Vascular and Pulmonary Diseases: Diagonsis and Management, Nov. 22-24, Sonesta Beach Hotel, Key Biscayne. Contact: Stephen E. Mattingly, 5808 S. Rapp Street, Littleton, Co 80120, (303) 798-9682.

DECEMBER

Techniques of Therapeutic Gastrointestinal Endoscopy, December 4-6, Contemporary Resort Hotel, Lake Buena Vista. For info: H. Worth Boyce Jr., M.D., USF College of Medicine, Box 19, 12901 N. 30th Street, Tampa 33612 (813) 974-2034.

Innovative and Controversial Strategies in Rehabilitation II: Technology and Techniques, Dec. 4-8, Sheraton Bal Harbour, Miami. Contact: Gloria Allington, P.O. Box 016960, Miami, Fl. 33101, (305) 547-6716.

Clinical Allergy and Immunology for the Practicing Physician, Dec. 5-7, Palace Hotel, Lake Buena Vista. For info: Richard F. Lockey, M.D., VA Hospital, 13000 N. 30th St., Tampa, 33612, (813) 972-2000, ext.596.

Ear, Nose, & Throat Diseases in Children, December 7-11, The Breakers, Palm Beach. For information: 125 DeSoto Street, Piladelphia, PA 15213, 412-647-5466.

Emergencies in Internal Medicine, VIII, Dec. 8-14, St. Thomas, Virgin Islands. For more information: Gloria Allington, P.O. Box 016960, Miami, Fl. 33101, 305-547-6716.

New Approaches to Common Disorders II, Dec. 11-14, Clearwater Beach. For information: Joel Gleason, M.D., 12901 N. 30th Street, Tampa, Florida 33612, (813) 397-5511.

JANUARY

Thirty-first Annual Cardiovascular Seminar, Jan. 10-11, Sheraton Sand Key Resort, Clearwater Beach. Contact: Anita Godsey, P.O. Box 7188, St. Petersburg, FL 33734, (813) 526-6000.

Omni-Specialty Medical Update, Jan. 12-14, Naples Bath and Tennis Club, Naples. Contact: James Marion, M.D.

The Economic Impact: Drug Abuse in the Work Force, Jan. 15-17, James L. Knight International Club, Miami. Contact: Conference Center, 400 S.E. 2nd Avenue, Miami, FL 33131, (305) 372-0140.

Eighteenth Annual Postgraduate Seminar in Pediatric and Adulat Urology, Jan. 15-18, Sheraton Bal Habor, Miami Beach. Contact: Victor A. Poktano, M.D., Dept. of Urology, 6614 Miami Lakes Drive East, Miami Lakes, FL 32014, (305) 687-1367.

Cardiology Tutorials in the Wilderness, Jan. 18-25, Canoe Trip, Everglades. Contact: Peter E. Pool, M.D., UCSD School of Medicine, La Jolla, CA 92093, (619) 452-3940.

Eleventh Annual Review and Recent Practical Advantages in Pathology, Jan. 19-24, Hyatt Hotel, Miami. Contact: A. Morales, M.D., P.O. Box 016960, Miami, FL 33101, (305) 549-6437.

Symposium on Cancer Biology and Therapeutics, Jan. 20-22, Curtis Hixon Convention Center, Tampa. Contact: J. G. Cory, Ph.D., Medical Center, Box 46, 12901 N. 30th Street, Tampa, FL 33612.

MedTech '86, Jan. 20-22, Curtis Hixon Convention Center, Tampa. Contact: International Conference Management, c/o The Madison, 15851 Dallas Parkway, Suite 1155, Dallas, TX 75248, (214) 458-7011.

Annual Symposium on Cancer Biology and Therapeutics, Jan. 20-22, USF College of Medicine, Tampa. Contact: Joseph Cory, Ph.D., 12901 N. 30th Street, Tampa, FL 33612, (813) 974-4296. A Practical Approach to Solutions and Problems in Burn Care, Jan. 30-Feb 1, Clearwater Beach. Contact: C. Wayne Cruse, M.D., 12901 N. 30th Street, Tampa, FL 33612, (813) 974-4296.

Vascular and Pulmonary Diseases: Diagnosis and Management, Jan. 31-Feb. 2, Don Cesar Hotel, St. Petersburg. Contact: Stephen E. Mattingly, (303) 798-9682.

FEBRUARY

Ultrasound Integrated into Modern Ob-Gyn, Miami Beach. Contact: William A. Little, M.D., P.O. Box 016960, Miami, FL 33101, (305) 549-6944.

Internal Medicine — Selected Aspects, Feb. 1-8, Telluride, Colorado. Contact: Gloria Allington, P.O. Box 016960, Miami, FL 33101, (305) 547-6716.

Twelfth Annual Bail Conference in Anesthesiology, Vail, Colorado. Contact: Brian Craythorne, M.D., P.O. Box 016960, Miami, FL 33101, (305) 547-6411.

Controversies in Carcinoma of the Breast, Feb. 1-8, Snowmass, Colorado. Contact: Martin Silbiger, M.D., 12901 N. 30th Street, Tampa, FL 33612, (813) 974-2538.

Eighteenth Miami Winter Symposium — Advances in Gene Technology, Feb. 3-7, Hyatt Regency Hotel, Miami. Contact: William J. Whelan, P.O. Box 016960, Miami, FL 33101, (305) 547-6265.

Hair Replacement Surgery for the Beginner, Feb. 5-9, Miami Airport Hilton, Miami. Contact: Sorrel S. Risnik, M.D., 9065 S.W. 87 Ave., Suite 109, Miami, FL 33176, (305) 279-6060.

Twenty-third Annual Neuroophthalmology Course, Feb. 6-8, Sonesta Beach Hotel, Key Biscayne. Contact: Hilary Hose, 6125 S.W. 31 Street, Miami, FL 33155, (305) 667-7060. Pulmonary, Allergy and Infectious Diseases, Feb. 10-14, Palace Hotel, Lake Buena Vista. Contact: Udaya Prakash, M.D., 200 1st Street, S.W., Rochester, MN 55905, (507) 284-2511.

Pediatrics for the Practitioner, Feb. 14, USF College of Medicine, Tampa. Contact: Herbert Pomerance, M.D., 12901 N. 30th Street, Tampa, FL 33612, (813) 974-4214.

Conference on the Beach, Feb. 17-22, Daytona Hilton, Daytona Beach. Contact: Tariq Siddiqui, M.D., P.O. Box 1990, Daytona Beach, FL 32015, (904) 254-4051.

Pediatric Dermatology Seminar, Feb. 20-23, Eden Roc Hotel, Miami Beach. Contact: Guenter Kahn, 16800 N.W. 2nd Avenue #401, N. Miami Beach, FL 33169, (305) 652-8600.

Eleventh Annual Midwinter Seminar in Ob/Gyn, Feb. 26-March 1, St. Petersburg Beach. Contact: J. M. Ungram, M.D., 12901 N. 30th Street, Tampa, FL 33617, (813) 974-2088.

Eighteenth Teaching Conference in Clinical Cardiology, Feb. 26-March 1, Sheraton Bal Harbour, Bal Harbour, Contact: Michael S. Gordon, M.D., D-41, P.O. Box 016960, Miami, FL 33101, (305) 547-6491.

Health Care of the Elderly, Feb. 27-March 1, USF College of Medicine, Tampa. Contact: Eric Pfeiffer, M.D., 12901 N. 30th Street, Tampa, FL 33612, (813) 974-4355.

Current Concepts in Surgery of the Gastrointestinal Tract, Feb. 27-March 1, Diplomat Hotel, Hollywood. Contact: 6614 Miami Lakes Drive East, Miami Lakes, FL 33014, (305) 687-1367.

Surgical Anatomy of the Eyelids, Orbit and Lacrimal Apparatus, Feb. 27-March 1, Lincoln Hotel and USF College of Medicine, Tampa. Contact: Jay J. Older, M.D., 12901 N. 30th Street, Tampa, FL 33612, (813) 974-3170.

MARCH

Neuroradiology: New Horizons and Current Concepts fo Classic Issues, March 3-7, Sheraton Bal Harbour, Miami. Contact: Joyce E. Freeman, P.O. Box 016960, Miami, FL 33101 (305) 549-6894.

Twenty-First Annual Meeting of the American Society of Contemporary Medicine and Surgery, March 9-13, Diplomat Hotel, Hollywood. Contact: John G. Bellows, M.D., 211 E. Chicago Ave., Sute 1044, Chicago, IL 60611, (312) 787-3335.

Breast Disease Update III, March 12-16, Hilton Hotel, Lake Buena Vista. Contact: Noel Zusmer, M.D., 4300 Alton Road, Miami Beach, FL 33140, (305) 674-2418.

Eighth Annual Family Practice Review, March 17-21, Adam's Mark Caribbean Gulf Resort, Clearwater Beach. Contact: Charles Aucremann, M.D., 701 6th Street South, St. Petersburg, FL 33701, (813) 893-6156.

APRIL

Vascular and Pulmonary Diseases: Diagnosis and Management, March 21-23, Bahia Mar Hotel, Ft. Lauderdale. Contact: Stephen E. Mattingly, (303) 798-9682.

Radiology of Hepatobiliary and Pancreatic Disease: Imaging and Intervention, April 1-5, Miami Hyatt Regency, Miami. Contact: Jill Nolden, Division of Diagnostic Radiology, P.O. Box 016960, Miami, 33101, (305) 549-6894.

1986 Radiation Therapy Seminar, April 17-19, University Centre Hotel, Gainesville. Contact: Division of Radiation Therapy, JHMHC J-385, Gainesville, 32610.

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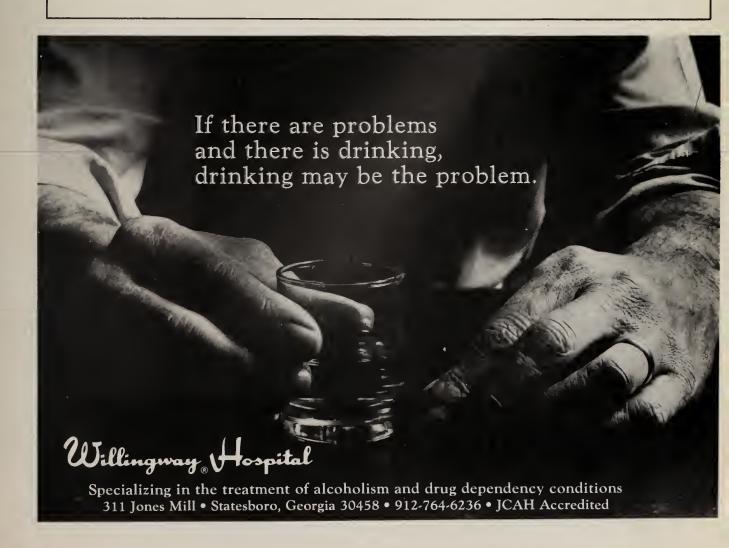
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MEMBERSHIP MEETING

Saturday, November 16, 1985

Hyatt Orlando

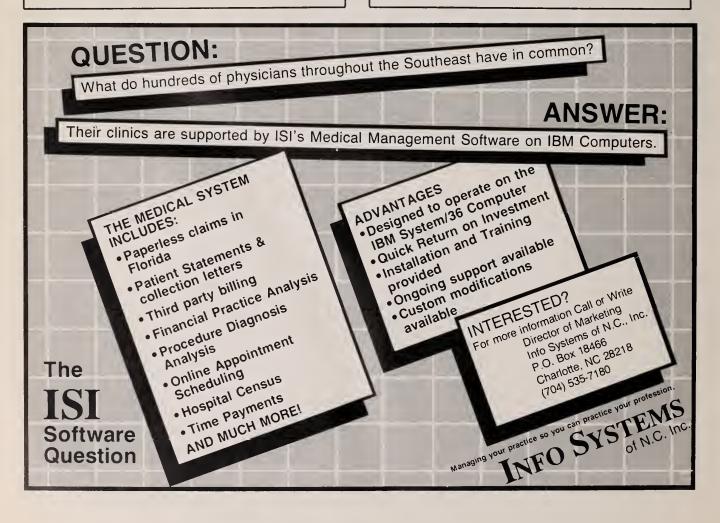
6375 W. Space Coast Parkway

10:00 — 12:00 noon Board of Directors Meeting Lunch

1:00 — 1:30 Business Meeting

1:30 — 2:45 "Indigent Maternity Care Update"

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Precoutions: in elderly and debilitated patients, it is recammended that the dasage be limited to 15 mg to reduce risk of aversedation, dizziness, confusion and/or atoxia. Consider patential additive effects with other hypnotics or CNS depressons. Emplay usual precoutions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepotic function.

Adverse Reactians: Dizziness, drawsiness, lightheadedness, staggering, afaxia and falling have accurred, particularly in elderly ar debilitated patients. Severe sedatian, lethargy, disarientation and cama, probably indicative at drug intalerance or averdasage, have been reparted. Alsa reported headache, heartburn, upset stamach, nausea, vamiting, diarrihea, canstipatian, Glipain, nervausness, talkativeness, apprehensian, irritability, weakness, palpitations, chest pains, bady and jaint pains and GU camplaints. There have alsa been rare accurrences at leukapenia, granulacytapenia, sweating, flushes, difficulty in facusing, blurred visian, burning eyes, faintness, hypotensian, shartness of breath, pruritus, skin rash, dry mauth, bitter taste, excessive salivatian, anarexia, eupharia, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, tatal and direct bilirubins, and alkaline phasphatase; and paradaxical reactions, e.g. excitement, stimulatian and hyperactivity

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